



# PEPFAR

U.S. President's Emergency Plan for AIDS Relief

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## **VMMC Notifiable Adverse Events DATIM Data Entry Guide**

**November 2021**

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## Introduction

In the summer of 2021, the Voluntary Medical Male Circumcision Notifiable Adverse Event Reports (VMMC\_NAE) were converted from a PDF form into a DATIM Tracker Capture event report form. All new VMMC Notifiable Adverse Events should now be entered, tracked, and submitted in DATIM.

## Access for DATIM Users

DATIM users will need access to the MCAE Data Stream to View and/or Enter VMMC\_NAE data. As a note, VMMC\_NAE Data is labeled “MCAE” in the DATIM User Administration App because of character length limitations – MCAE stands for Medical Circumcision Adverse Events.

		DATIM User Types													
Data Stream Name	DATIM User Admin Data Stream Type	MOH	MOH UA	Partner	Partner UA	Agency	Agency UA	Inter Agency	Inter Agency UA	Global Partner	Global Partner UA	Global Agency	Global Agency UA	Global	Global UA
VMMC_NAE	MCAE View Data	None	None	Select	Auto	Select	Auto	Select	Auto	Auto	Auto	None	None	Select	Auto
	MCAE Enter Data	None	None	Select	Auto	Select	Auto	None	None	None	None	None	None	Select	Auto
KEY	Auto	Data stream access type is automatically given to this user type, and it is unable to be removed													
	Select	User Administrator can add or remove this access through the DATIM User Admin App													
	None	The user has no access to VMMC_NAE data													

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

# VMMC\_NAE General “Quick Tips” for DATIM Tracker

## Create a PDF

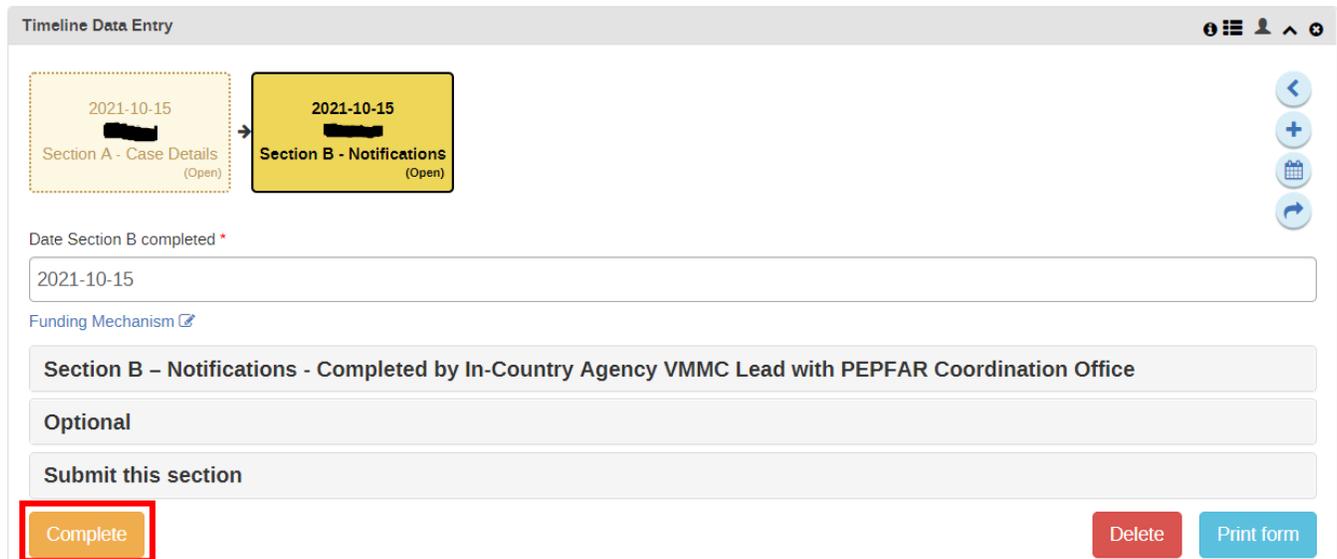
To create a PDF of your VMMC\_NAE report (either what has been entered so far, or the finished report up to Section E) go to the "Report" widget at the bottom of your Tracker capture VMMC NAE Report > click where it says "VMMC Notifiable Adverse Events Tracker" > then scroll all the way to the bottom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



## Notification and Submission

There are two notification and submission processes to be aware of for VMMC NAE reporting:

1. Any users required to alert their In-Country Agency VMMC Lead(s), PEPFAR Coordinator, or any other necessary parties in country - as appropriate – should use email to send these notifications. It is recommended that any notification include the OU name and VMMC Unique ID number.
2. After entering data in a section, clicking the “Complete” button in the “Timeline Data Entry” box will close the section and automatically submit a notification to S/GAC HQ. If any questions or clarifications need to be sent to S/GAC before completing a section in DATIM, users should email VMMC\_AE@state.gov directly.

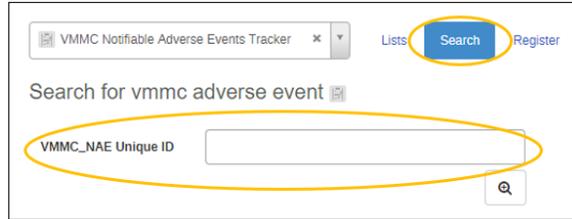


## Data Entry

Voluntary Medical Male Circumcision Notifiable Adverse Event (VMMC\_NAE) reporting data entry can be found in the DATIM **Tracker Capture App**.

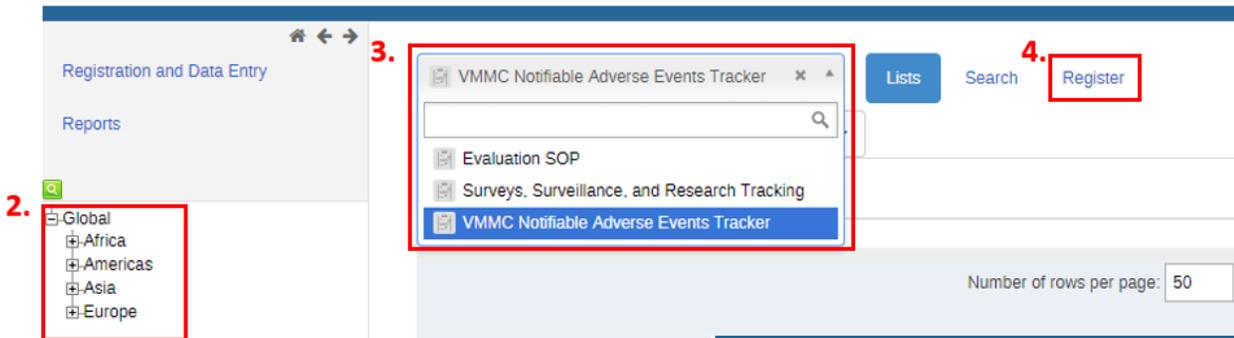
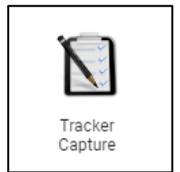
### Find an existing VMMC\_NAE Report

To look up an existing VMMC\_NAE Report, use the “Search” button to search the VMMC\_NAE Unique ID.

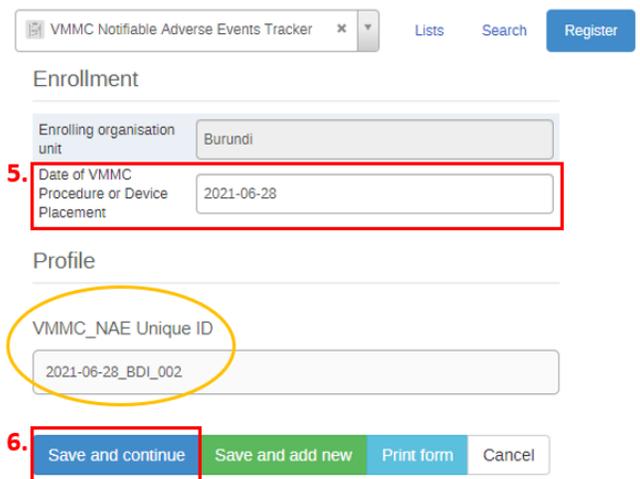


### Creating a new VMMC\_NAE Report

1. Navigate to the Tracker Capture App in DATIM. 
2. Once the Tracker Capture App loads, select the appropriate OU hierarchy (OU) from the left side tree. *VMMC\_NAE is only available at the OU Level (i.e. Country, NAT, National, etc)*
  - Global users may need to expand the OU tree using the small + buttons to the left.
3. Then select “VMMC Notifiable Adverse Events Tracker” from the drop down in the middle of the page.
4. Click “Register” to start a new adverse event report.



5. Next, you’ll be taken to the “Enrollment” screen. Once the “Enrollment” page loads, enter the date of the VMMC procedure or device placement.
  - *Note, it will auto-populate with today’s date, but it should be changed to the date of the procedure or device placement.*
6. Click “Save and Continue” to begin data entry.



\*The “VMMC\_NAE Unique ID” is automatically generated by the system and should be used to reference the report you are creating. Please note this ID for future reference, as other identifying characteristics will not be visible for searching at a later date.

## Section A – Case Details

After creating/enrolling a new VMMC\_NAE report, the Tracker Capture data entry dashboard will load. START: To begin Section A, Implementing Partners should navigate to the “Timeline Data Entry” section:



1. 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 VMMC procedure or device placement date previously occurred under an expired funding mechanism.*
  - c. Today’s date should auto-populate.

Add new event for stage **Section A - Case Details**

<b>a.</b> Program stage	Section A - Case Details
<b>b.</b> Funding Mechanism	Select or search from the list
<b>c.</b> Date Section A completed	2021-06-29

2. Click “Save”, and the Section A data entry fields will load.
3. Enter all required and relevant data.
  - a. Do not include any Personally Identifiable Information (PII)! This includes the names, initials, and contact information of clients or their guardians/family members.
  - 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 S/GAC HQ that Section A has been completed.
  - a. To EDIT the section after it has been closed, click the “Incomplete” button, make the necessary changes, then click the “Complete” button again.
    - i. *HINT – You can also add a note to describe any edits made to the report*

### **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 [VMMC\\_AE@state.gov](mailto:VMMC_AE@state.gov). Technical issues should be sent to [DATIM Support](#).
- Do not include Personally Identifiable Information (PII), including the names, initials, and contact information of clients or their guardians/family members.

## Section B – Notifications

Within 24 hours of receipt of Section A, the In-Country Agency VMMC Lead must notify the PEPFAR Coordinator and all necessary parties in country as appropriate and record those notifications in Section B. Section B can only be loaded after Section A has been generated.

To add Section B, Agency users will have to navigate to the “Timeline Data Entry” widget after searching for the VMMC\_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.

Funding Mechanism 

Section A: Case Details

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

Add new event for stage Section B - Notifications

a.	Program stage	Section B - Notifications
b.	Funding Mechanism	Select or search from the list
c.	Date Section B completed	2021-06-29

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 S/GAC HQ that Section B has been completed.
  - a. To EDIT the section after it has been closed, click the “Incomplete” button, make the necessary changes, then click the “Complete” button again.
    - i. *HINT – You can also add a note to describe any edits made to the report*

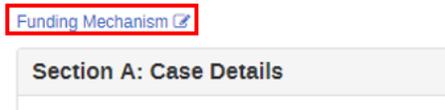
### Section B Quick Tips

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

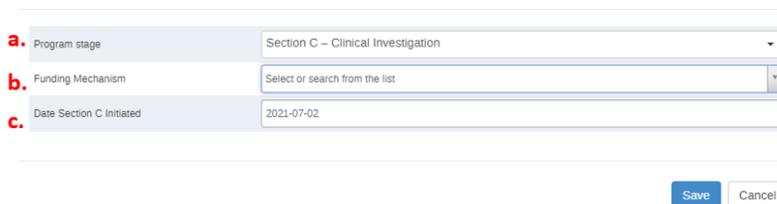
## Section C – Clinical Investigation

To add Section C, the PEPFAR In-Country Incident Lead will have to navigate to the “Timeline Data Entry” widget after searching for the VMMC\_NAE Unique ID in the Tracker Capture App. Section C can only be loaded after Section B has been generated.

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 will auto-populate it when generating the next section.



- c. Today’s date should auto-populate
- Add new event for stage Section C – Clinical Investigation



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. Attachments: The data tracker app will not support attached documents (e.g., lab results, pictures) at this time, please submit any attachments to the VMMC\_AE@state.gov inbox and reference the appropriate VMMC\_NAE Unique ID in the email. Please remember to redact any PII contained in the attachments.
5. Once the investigation is complete, clicking “Complete” will close the section and automatically submit a notification to S/GAC HQ that Section C has been completed by all parties.
  - a. To EDIT the section after it has been closed, click the “Incomplete” button, make the necessary changes, then click the “Complete” button again.
    - i. *HINT – You can also add a note to describe any edits made to the report*

### **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
- *Do not include Personally Identifiable Information (PII)*, including the names, initials, and contact information of clients or their guardians/family members.
- Attachments can be sent to [VMMC\\_AE@state.gov](mailto:VMMC_AE@state.gov)
- Any guidance questions or concerns about the information being requested can be emailed to [VMMC\\_AE@state.gov](mailto:VMMC_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 S/GAC VMMC Consulting Physician/Clinician, with responses entered by the VMMC In-Country Incident Lead. Section C Q&A can only be loaded after Section C has been generated.

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 Optional Q & A
  - 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.

Funding Mechanism 

### Section A: Case Details

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

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

<b>a.</b> Program stage	Section C - Optional Q & A
<b>b.</b> Funding Mechanism	Select or search from the list
<b>c.</b> Date Section C Q&A Initiated	2021-07-02

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 S/GAC HQ that Section C Q & A has been completed.
  - a. To EDIT the section after it has been closed, click the "Incomplete" button, make the necessary changes, then click the "Complete" button again.
    - i. *HINT – You can also add a note to describe any edits made to the report*

### **Section C – Optional Q & A Quick Tips**

- Section C is completed by the S/GAC VMMC Consulting Physician/Clinician, with responses entered by the VMMC In-Country Incident Lead
- *Do not include Personally Identifiable Information (PII)*, including the names, initials, and contact information of clients or their guardians/family members.
- Clicking "Complete" will automatically submit Section C Optional Q&A to S/GAC HQ. However, any questions or concerns can be emailed to [VMMC\\_AE@state.gov](mailto:VMMC_AE@state.gov). Technical issues should be sent to [DATIM Support](#).

## Section D – HQ Assessment

Section D is completed by the S/GAC VMMC Consulting Physician/Clinician. Section D can only be loaded after Section C has been generated.

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.

Funding Mechanism 

### Section A: Case Details

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

Add new event for stage Section D - HQ Assessment

a.	Program stage	Section D - HQ Assessment
b.	Funding Mechanism	Select or search from the list
c.	Date Section D completed	2021-07-02

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 S/GAC HQ that Section D has been completed.
  - a. To EDIT the section after it has been closed, click the “Incomplete” button, make the necessary changes, then click the “Complete” button again.
    - i. *HINT – You can also add a note to describe any edits made to the report*

### **Section D Quick Tips**

- Section D is completed by the S/GAC VMMC Consulting Physician/Clinician
- *Do not include Personally Identifiable Information (PII)*, including the names, initials, and contact information of clients or their guardians/family members.
- Clicking “Complete” will automatically submit Section C Optional Q&A to S/GAC HQ. However, any questions or concerns can be emailed to [VMMC\\_AE@state.gov](mailto:VMMC_AE@state.gov). Technical issues should be sent to [DATIM Support](#).

## Section E – Report Finalization

ONLY the S/GAC 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
  - 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.

Funding Mechanism 

### Section A: Case Details

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

Add new event for stage **Section E – Report Finalization**

<b>a.</b> Program stage	Section E – Report Finalization
<b>b.</b> Funding Mechanism	Select or search from the list
<b>c.</b> Date Section E completed	2021-07-02

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 VMMC\_NAE report.
  - a. To EDIT the section after it has been closed, click the “Incomplete” button, make the necessary changes, then click the “Complete” button again.
    - i. *HINT – You can also add a note to describe any edits made to the report*