eHealth Saskatchewan

PANORAMA

User Guide

IMMUNIZATION

Adverse Event Following Immunization

- **Overview of the Adverse Event Record**
- **View Adverse Event**
- **Create Adverse Event**
- **Delete Adverse Event**

Revision History

Document History

Date	Version	Author	Changes / Comments
September 3, 2014	V0.1	Josie Salvail	Initial Draft
September 15, 2014	V0.2	Tracy Forbes	Minor updates
November 5, 2014	V0.3	Tracy Forbes	Aligned to SK process, and updated with recommendations to address gaps/changes between existing AEFI paper form and Panorama AEFI.
November 6, 2014	V1.0	Tracy Forbes	Included final updates from Loretta Van Haarlem and incremented to V1.0.
January 20, 2015	V1.1	Tracy Forbes	Cleared dates footers

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NOTE: This user guide shows how to complete the AEFI Report in Panorama. It is important for all users to follow Saskatchewan policy and procedures when creating and reviewing an AEFI Report.

A. Introduction

The purpose of the Adverse Event functionality is to allow authorized Users to record/update Adverse Event Following Immunization (AEFI) information in the system and link it to specific Immunization Records when an AEFI has been reported to Public Health.

Regional Health Authority public health staff receive reports on AEFIs from clients, the parents or guardians of clients and from non-public health immunizers.

Within each RHA, the nurse creating the "draft" report will record the details and once all necessary information is recorded in the AEFI record in Panorama, selects "Submitted for Review" and the Workgroup for Review & Approve AEFI. This causes a system automated Task to be sent to the RHA Nursing Manager or Immunization Program Coordinator responsible requesting to approve the AEFI record meets expected quality/completeness of data and adherence to AEFI case definition criteria.

If approved, he/she selects "Submitted for Review" along with the Workgroup for "MHO AEFI Review" and a system automated Task will be sent to the regional MHO for his/her review, further testing or follow-up as required, and recording of the final recommendation as to how to proceed in the future with respect to the involved antigens.

Once the MHO has completed review and recommendations the record will be set to Completed, and a system-automated Task will be created for the AEFI submitter, in order to follow up with the Client or parents/guardian as well as to create any Special Consideration records required by the MHO's recommendation.

High level steps are:

1. Draft AEFI (Submitter)
2. Submit for Review – AEFI Review & Approve WG notified
3. Reviewed & approved, Submit for Review to MHO – AEFI MHO Review & Recommend WG notified
4. Reviewed and recommendations recorded – Set to Complete – AEFI Submitter WG notified

Assumptions: The user has the appropriate security permissions to perform the assigned tasks. Only immunization events which meet one or more of the criteria below should be recorded as potential AEFIs:

- Of a serious nature
- Require urgent medical attention
- Unusual or unexpected
- Temporally associated with vaccination

Pre-requisites: To complete the steps within this user guide, the user must have the appropriate permissions and security access. User is in the Immunization module (tab), and has a client in context. The immunization related to the adverse event must be in the client's immunization record (within the Client Immunization Profile). Workgroups exist with the specific users required to submit, approve, review and recommend, complete and potentially report the AEFI to PHAC.

Related User Guides: Add Immunizations, Add Special Consideration.

B. Overview of the Adverse Event Report

The AEFI report is a multi-section electronic record. Each section can be expanded to view or update the corresponding information. The information within this report does not need to be completed in a specific order.

The Adverse Event documentation may take some time to complete, and may involve contributions from multiple users. The system records the contributing user names and dates of those contributors within the **AE History**.

The **Assigned To** section allows the user to "pass" the document to another user by selecting Workgroup(s) for automated Task assignment. By assigning a Task to a Reviewer (this could be to a workgroup, or an individual within a workgroup), the **AE History** status changes. The status could be one of the following:

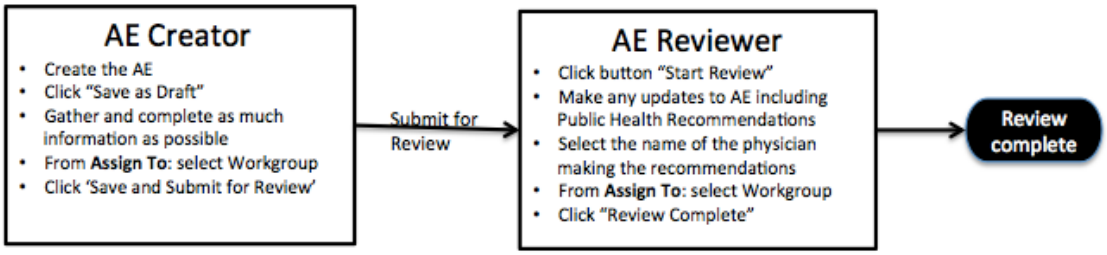
- Draft
- Submitted for Review
- Information Required
- Consultation Required
- Review Complete

TIP: The **Assigned To**: section requires the user to notify a Workgroup or user. This may be a group of individual users responsible for AEFI review and documentation. It is suggested that you notify (phone call / email) reviewers or other contributors that input is needed.

NOTE: Tasks are viewed and managed within the **Work Management** module.

NOTE: Once the AEFI Report has been given the Status "Submitted for Review", multiple users may contribute to the AE Report. The username and the date of the contribution are recorded in the AE History.

Minimum Workflow



C. View Adverse Event

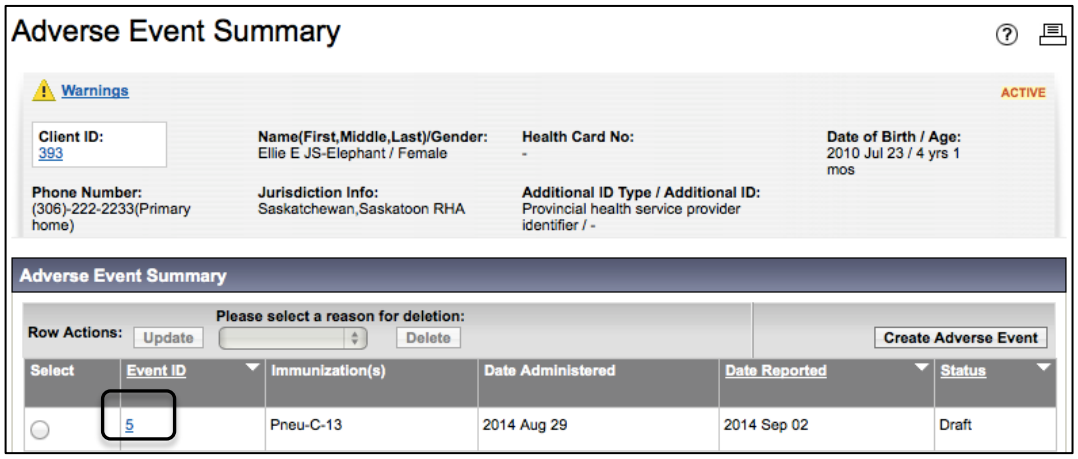
The **Adverse Event Summary** screen contains all of the AEFI records entered or deleted for the client.

Pre-requisites: The user has successfully logged into Panorama. User is in the Immunization module (tab). Client is in context.

Menu Access: Select Immunizations > Adverse Events (AEFI)

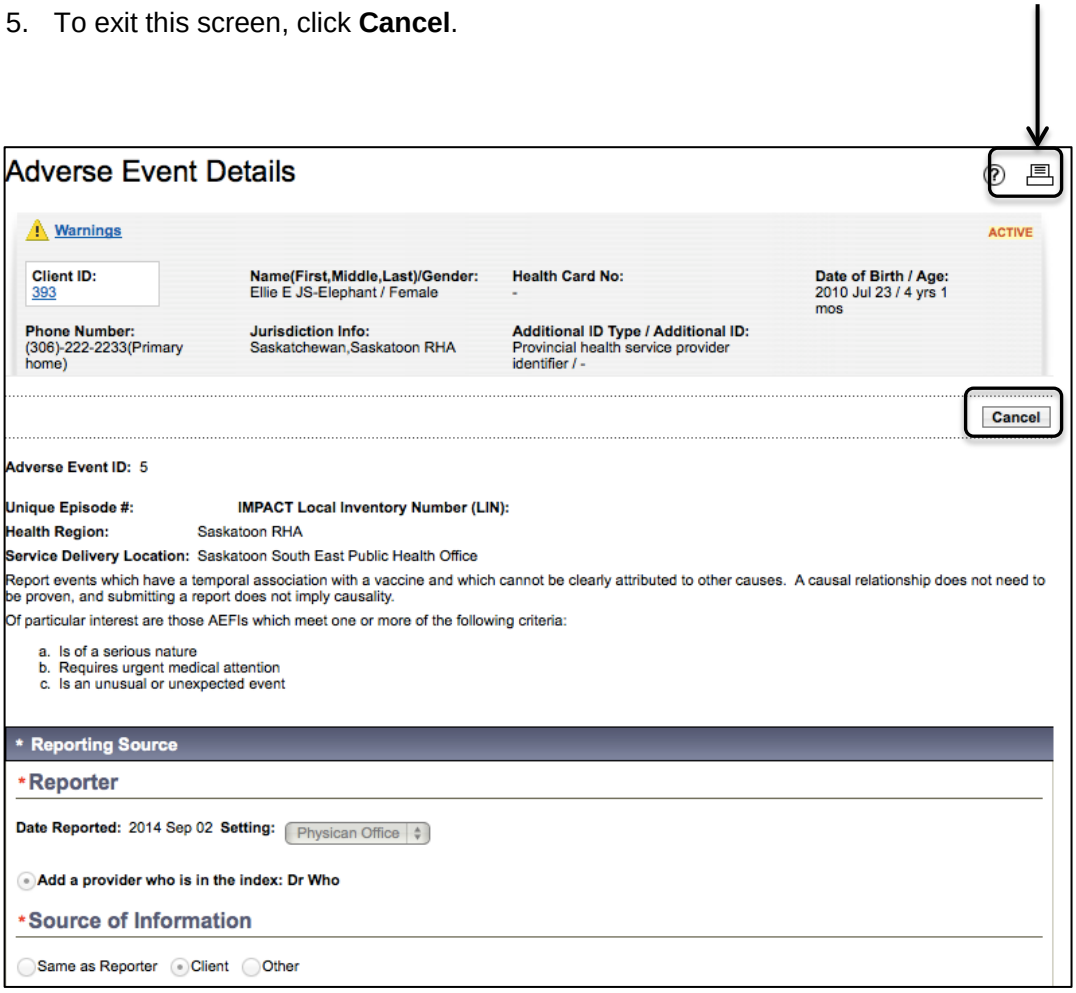
1. Click Immunizations > Adverse Events (AEFI) from the left navigation bar. The Adverse Event Summary screen displays.

2. To view an existing Adverse Event, click the **Event ID** hyperlink**.**



The **Adverse Event Details** screen displays.

3. View the AEFI details within each section.
4. To Print the AEFI Report, click on the Printer icon on the top right of the screen.
5. To exit this screen, click **Cancel**.



D. Create Adverse Event

The AEFI report is a multi-section electronic record. Each section can be expanded to view / update the corresponding information. The information within this report does not need to be completed in a specific order.

Pre-requisites: The user has successfully logged into Panorama. User is in the **Immunization** module (tab). Client is in context. The immunization (that has caused the adverse event) is recorded for the client. All required AEFI Workgroups have been set up for the RHA of the user.

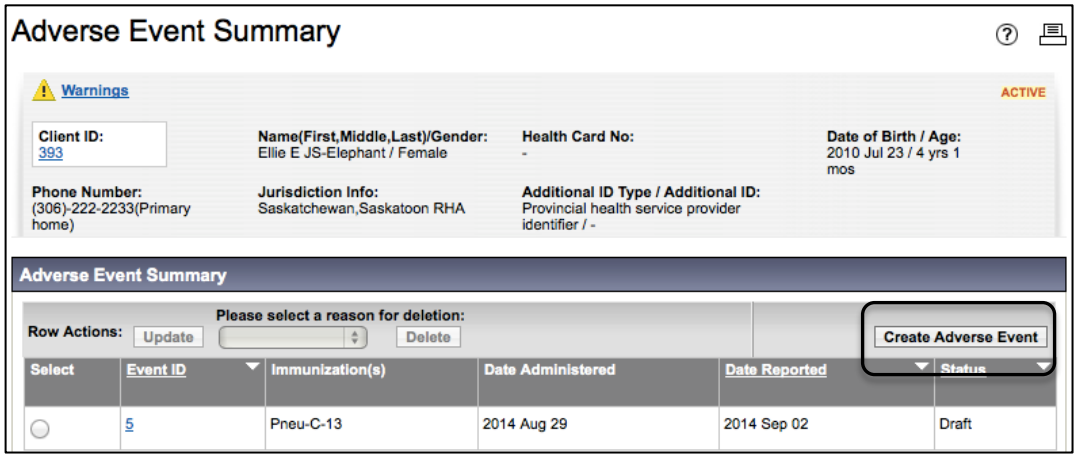
Menu Access: Select Immunizations > Adverse Events (AEFI)

1.0 Adverse Event Create

The Adverse Event Create process involves creating the AEFI Report in Panorama, and completing the form until all the information and mandatory fields are entered into the Report. The user will then click **Save and Submit** for review. Here are the steps:

1. Click Immunizations > Adverse Events (AEFI) from the left navigation bar.

   The Adverse Event Summary screen displays.

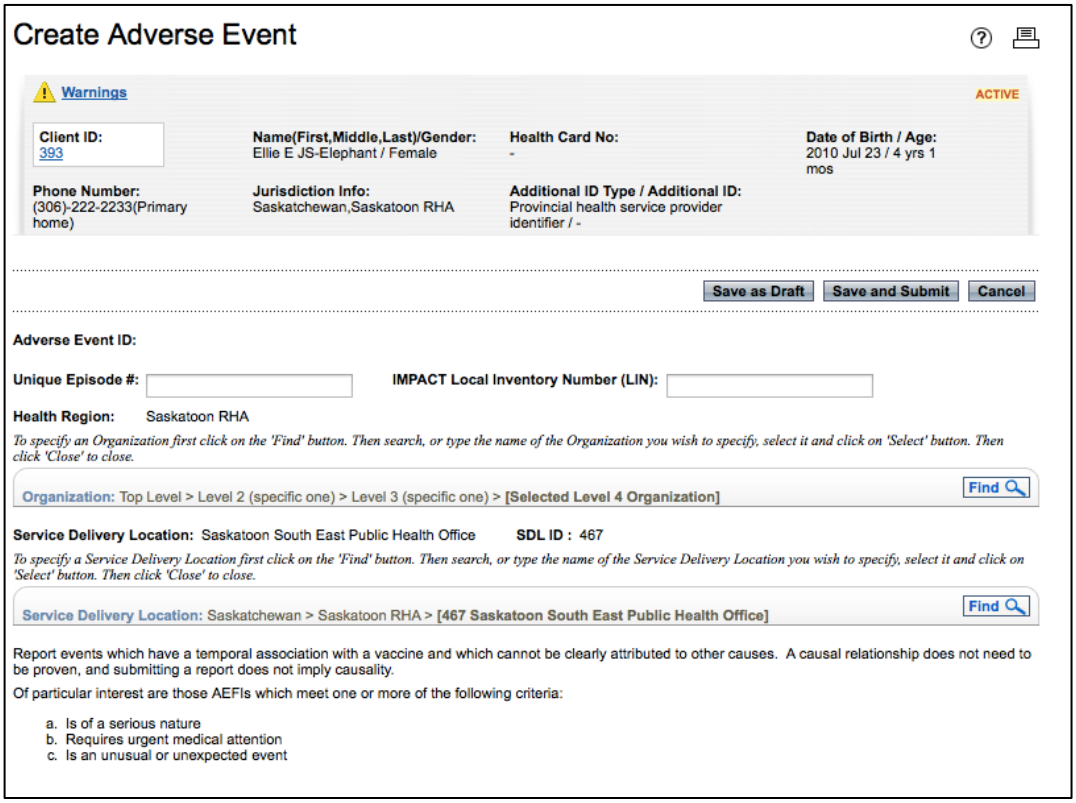


2. Click **Create Adverse Event**.

TIP: The user may save the AE Report at any time by clicking "Save as Draft" even if there are missing mandatory data. To do this, there are 2 required fields:

- Reporter - Who is reporting the AE
- Immunization that caused the AE.

The **Create Adverse Event** screen displays.



3. Add the **Unique Episode #** if this information is applicable / available. The recommended format is YYYY-##.

4. Add the **IMPACT Local Inventory Number (LIN)** if this information is applicable / available. Enter this number if the report was received from IMPACT; otherwise leave it blank. The number is used by the Public Health Agency of Canada to reconcile reports received both from the province and from IMPACT directly.

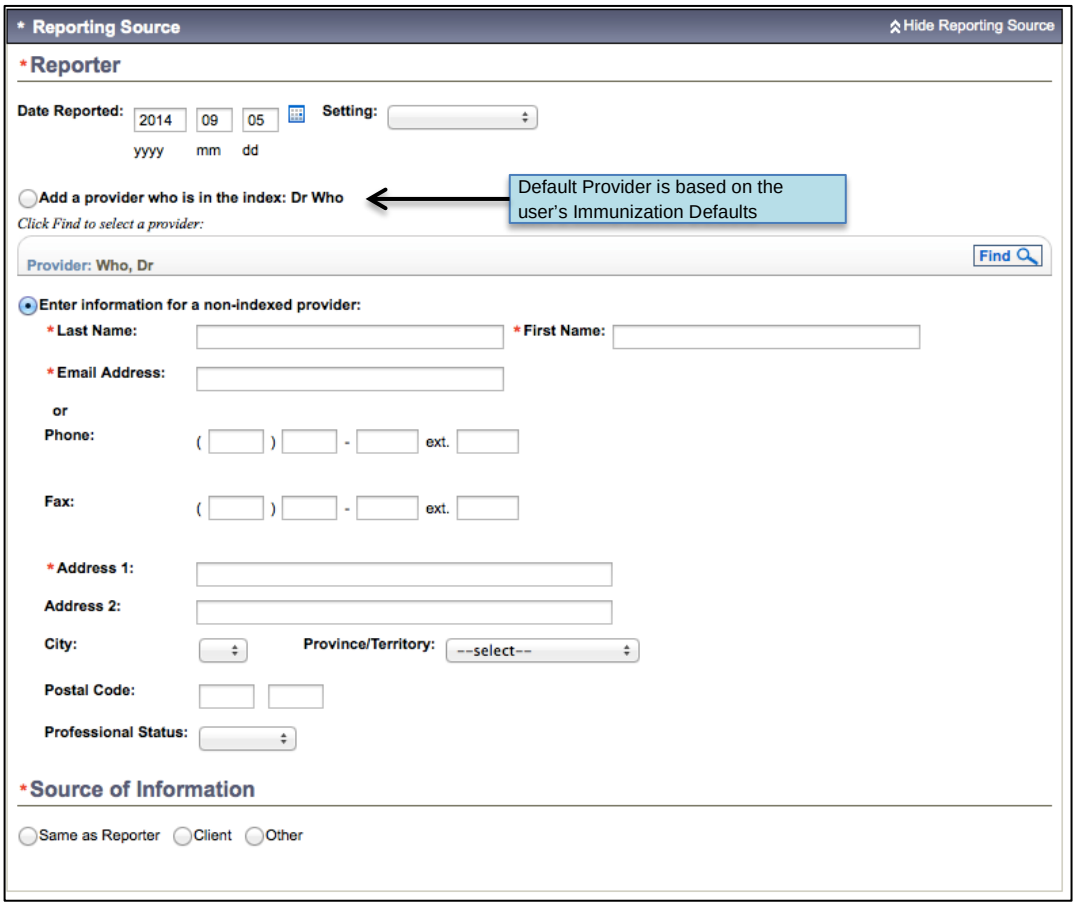
5. Update the **Health Region** if the default (user default) is not correct. To do this, click the **Find** button. Use the **Type** ahead or **Search** to locate the correct Health Region.

6. Update the **Service Delivery Location** if the default (user default) is not correct. To do this, click the **Find** button. Use the **Type** ahead or **Search** to locate the correct SDL.

TIP: The **Date Reported**, the **Reporting Source,** and the **Source of Information** are all required fields.

7. Update the **Date Reported** as required. The default is set to current date.

8. Select the AE **Setting** from the drop-list (e.g. Physician office, Public Health, etc.).



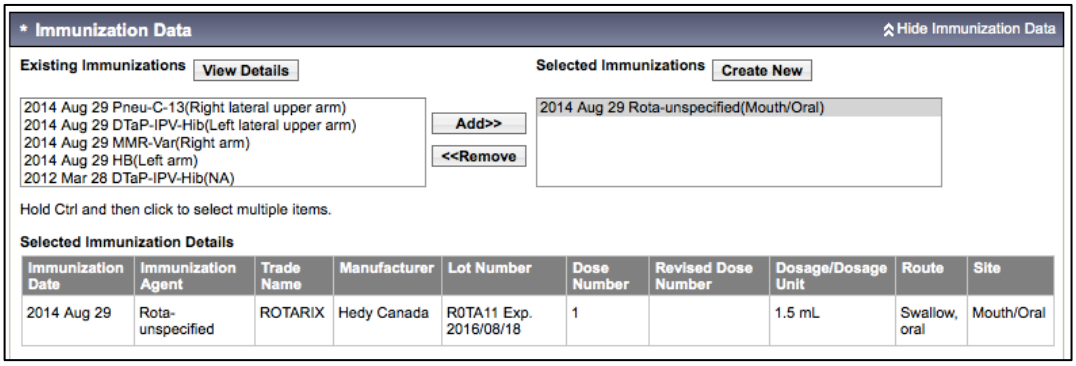
9. Select the **Provider** that is reporting the AE in Panorama. The default is the Provider set in the User's Immunization Defaults. To select a different Provider from the Index, click **Find**. Use the **Type** ahead or **Search** to locate the correct Provider. If the Provider is not in the Index, select the radio button **Enter information for a non-indexed provider**, and enter the provider information in the fields.

10. Select the **Source of Information** radio button.

TIP: The **Immunizing Agent** related to the AEFI is a required field.

11. Select the **Existing Immunization**(s) applicable to the adverse event.

12. Click **Add** to move the immunizing agent to the right hand box – **Selected Immunizations**, (or **Create New** to record the immunization details from the reporter).

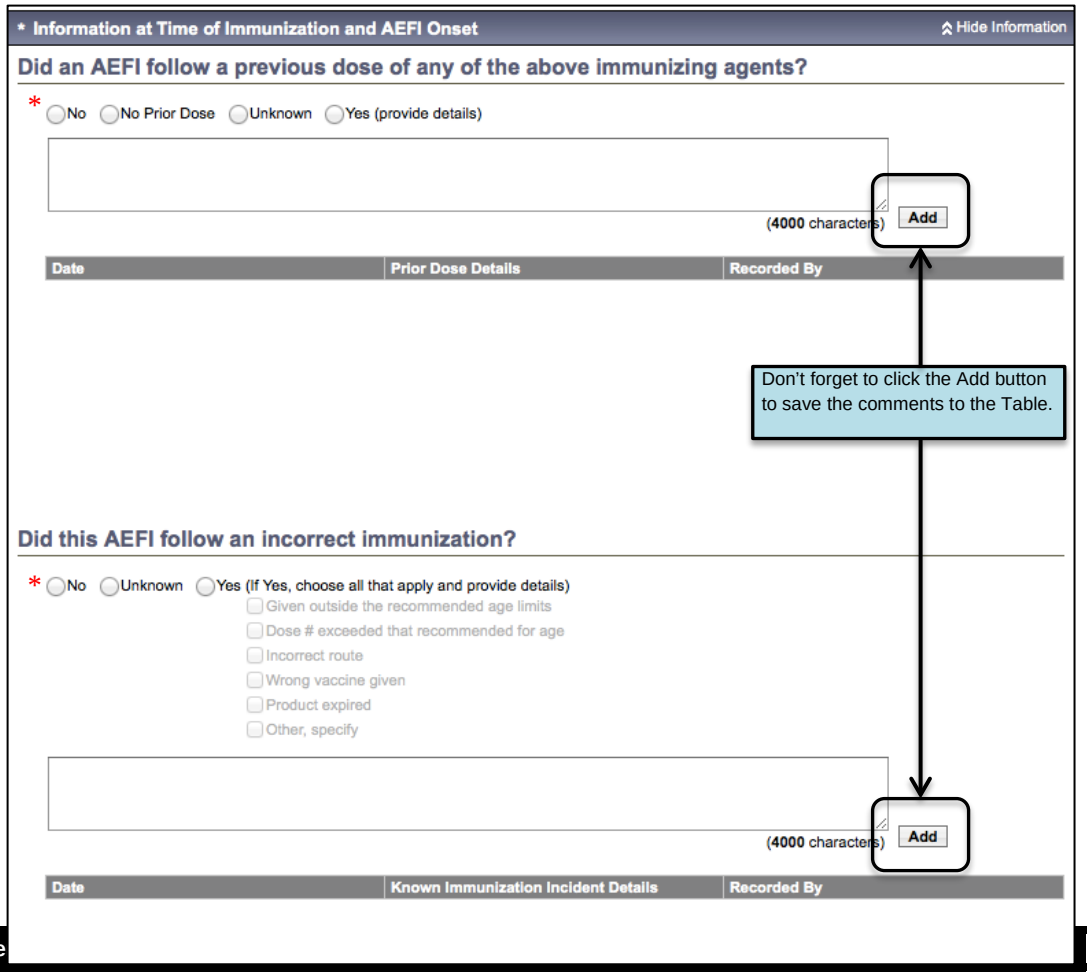


TIP: The user must answer these two questions (required fields) before the report may be 'Submitted for Review':

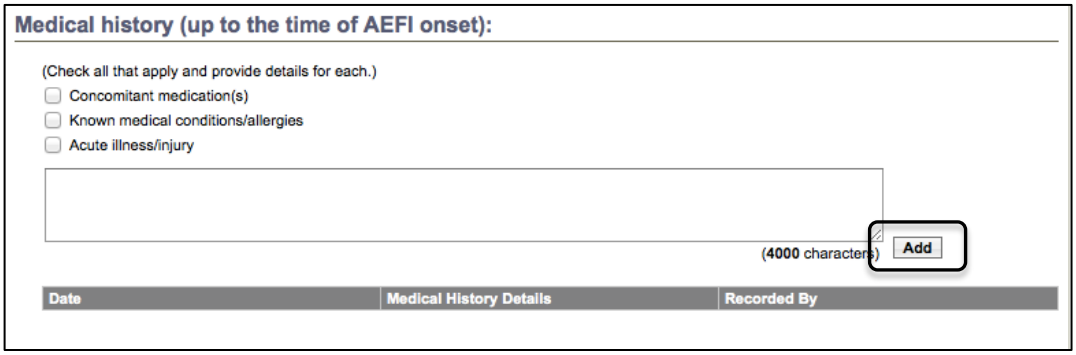
1) Did an AEFI follow a previous dose of any of the above immunizing agents?
2) Did this AEFI follow an incorrect immunization?

The **Selected Immunization Details** Table automatically populates the specific details of the immunization.

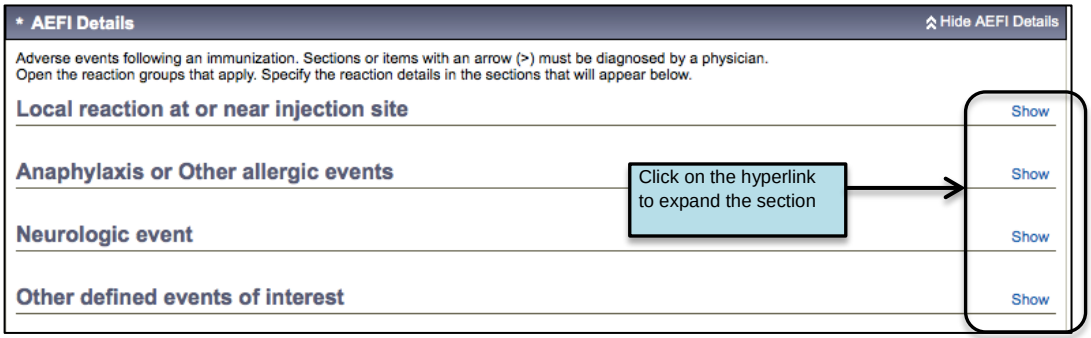
13. Enter **Information at time of Immunization and AEFI Onset**.



14. Select the **Medical history up to the time of AEFI onset**. Add any comments, and click **Add** to save them to the Table.



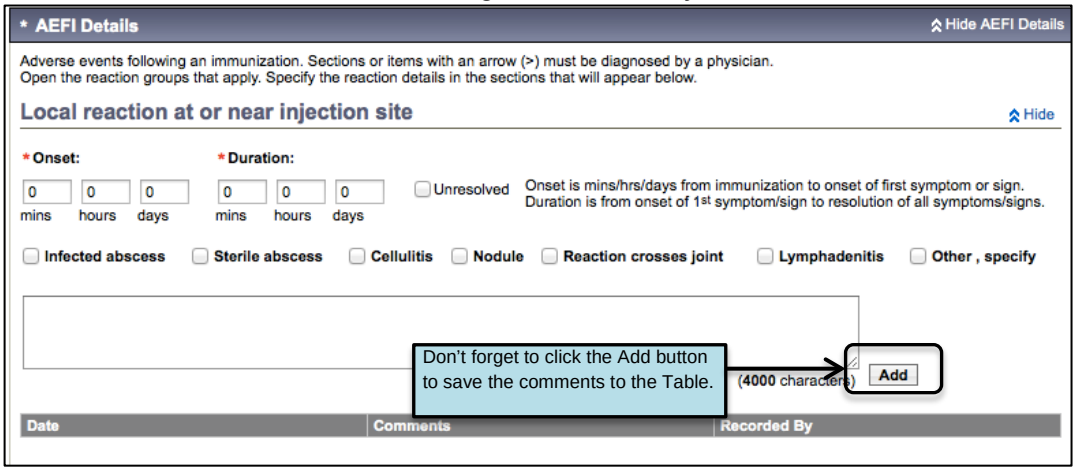
15. Open up the AEFI Details section to add information related to the type of reaction.



TIP: At least one of these sub-sections must be completed before the report can be 'Submitted for Review'.

16. Enter AEFI Details related to the **Local reaction at or near injection (vaccination) site**. Enter **Onset** time. Onset is mins/hrs/days from immunization to onset of first sign or symptom. If not yet resolved, select the Unresolved checkbox, and Duration will no longer be mandatory.

TIP: If the AEFI is related to a 'Local reaction at or near injection site', required fields are: **Onset** and **Duration**.

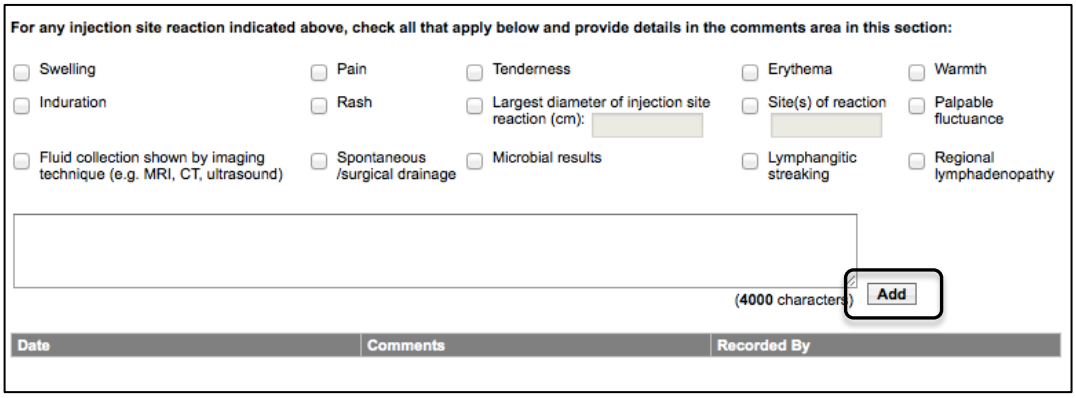


17. Enter **Duration** time. Duration is from onset of first symptom/sign to resolution of all symptoms/signs.

18. Click the checkboxes for any local reactions that apply. If the reaction is not listed, click **Other, specify**; and enter details of the reaction in the comments box. Click **Add** to save the comments to the Table.

19. Add any additional information about the reaction near the injection site. Add any additional comments in the comments box, and click **Add** to save them to the Table.

TIP: At any time, click **Save as Draft** to ensure updates to the screen are saved to the AEFI report.

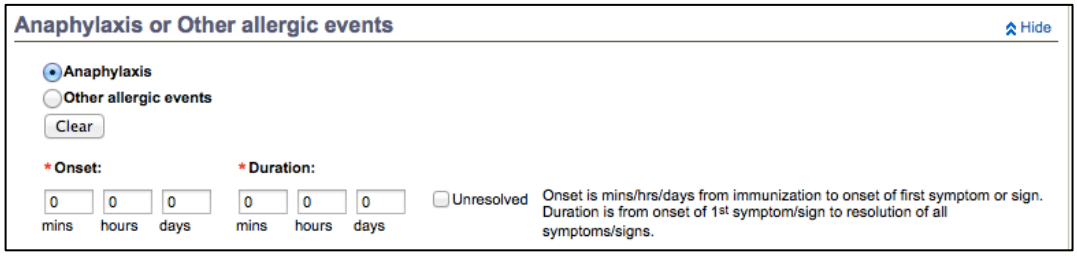


20. Enter AEFI Details related to **Anaphylaxis or Other allergic events**. Enter **Onset** time. Onset is mins/hrs/days from immunization to onset of first symptom or sign

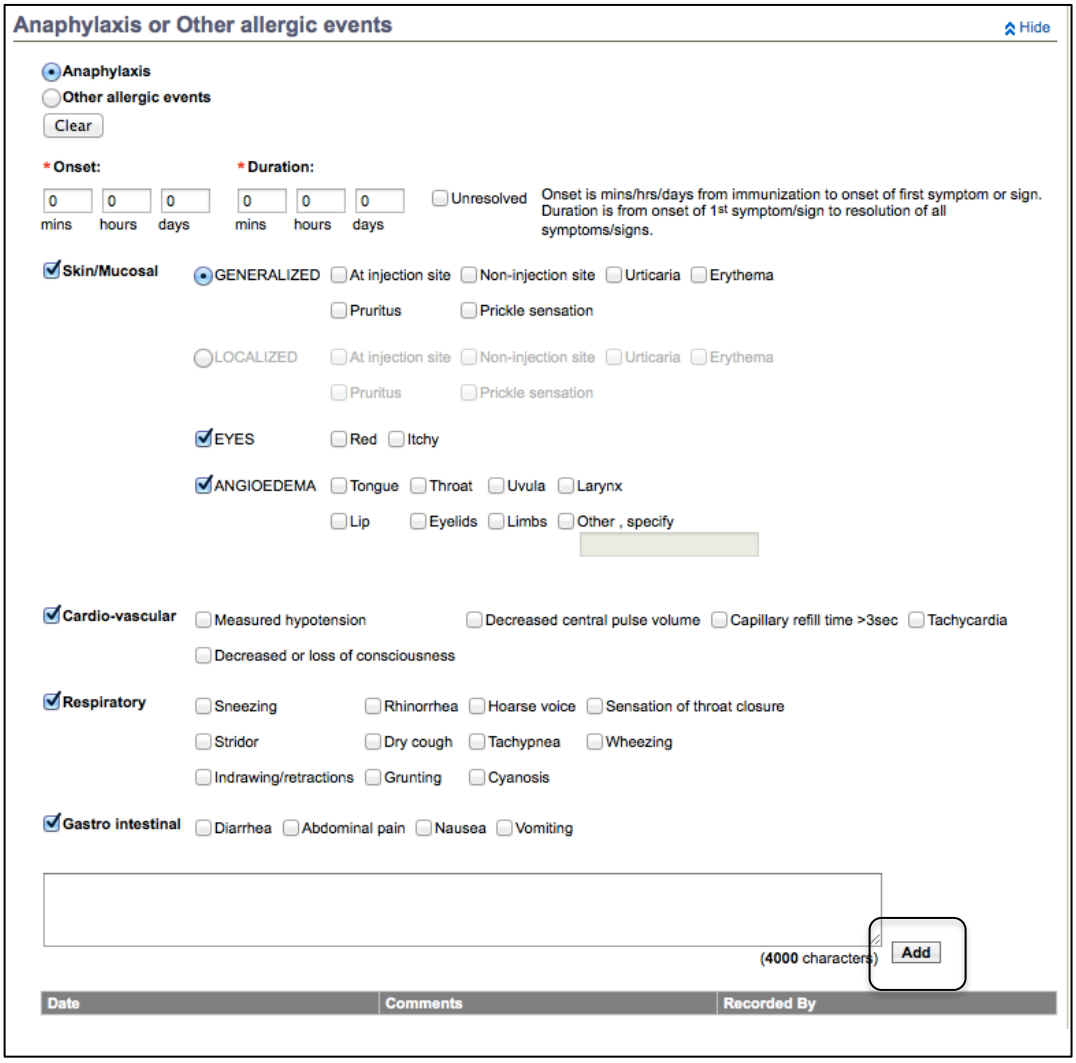
21. Enter **Duration** time. Duration is from onset of first symptom/sign to resolution of all symptoms/signs.

TIP: If the AEFI is related to 'Anaphylaxis or Other allergic events', required fields are: **Onset** and **Duration**.

TIP: The **Clear** button will deselect both the radio buttons above it.

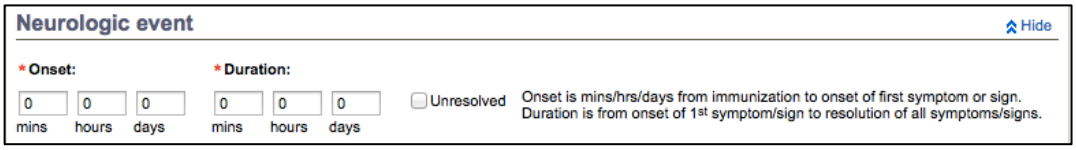


22. Click on any of the selections related to the Anaphylaxis or Other allergic events. Once you click on a sub-section (e.g. Skin/Mucosal), the descriptive options are available for selection. Add comments as required, and click **Add** to save the to the Comments Table.



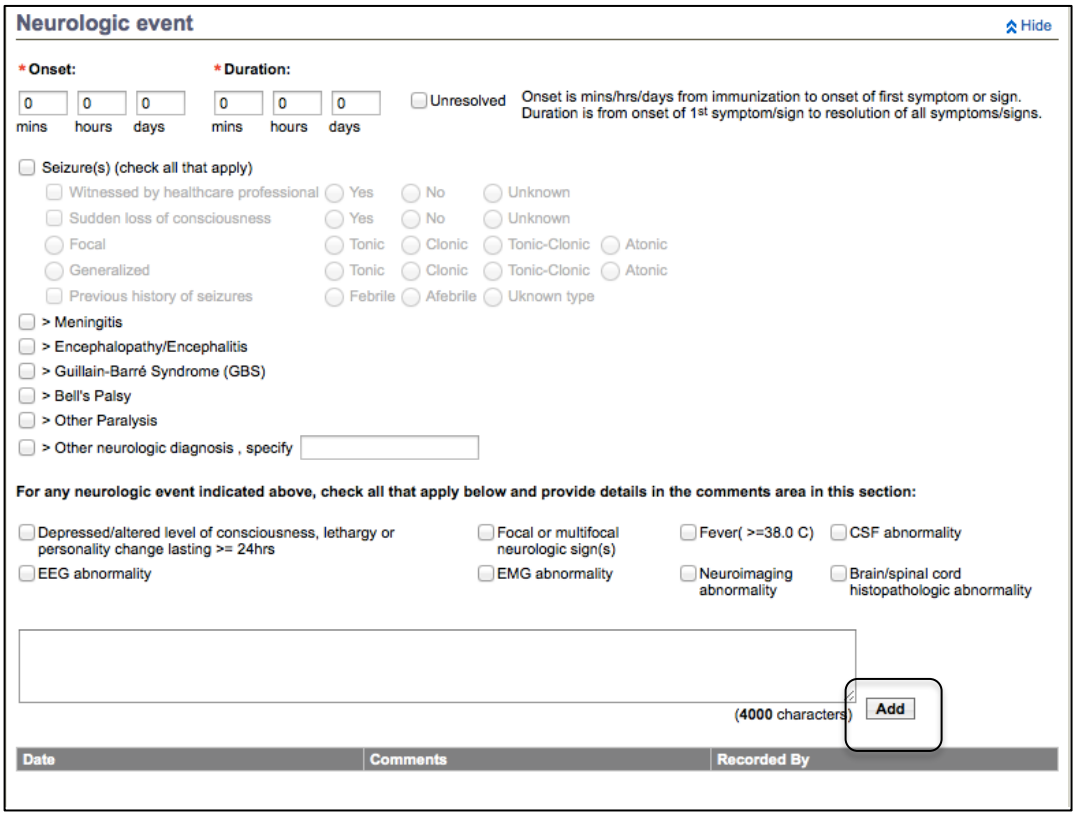
TIP: If the AEFI is related to a 'Neurologic event', required fields are: **Onset** and **Duration**.

23. Enter AEFI Details related to **Neurologic event.** Enter **Onset** time. Onset is mins/hrs/days from immunization to onset of first symptom or sign.



24. Enter **Duration** time. Duration is from onset of first symptom/sign to resolution of all symptoms/signs.

25. Click on any of the selections related to the Neurologic event. Once you click on a sub-section, the descriptive options are available for selection. Add comments as required, and click **Add** to save the to the Comments Table. Note: Use the Comment field of the Neurologic Event section to indicate: Absence, Myoclonic or



Partial seizure.

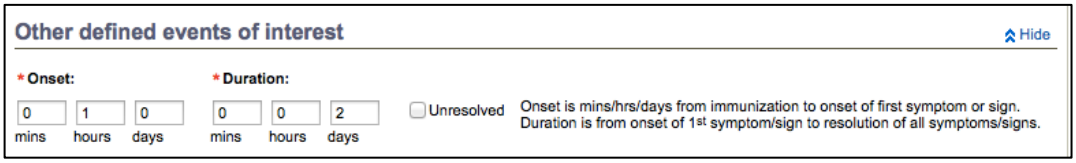
26. Enter AEFI Details related to **Other defined events of interest**. Enter **Onset** time. Onset is mins/hrs/days from immunization to onset of first symptom or sign.

Reminder: A fever needs to be greater than 38 degrees and present in conjunction with a reportable event.

1. Enter **Duration** time. Duration is from onset of first symptom/sign to resolution of all symptoms/signs.

TIP: At any time, click **Save as Draft** to ensure updates to the screen are saved to the AEFI report.

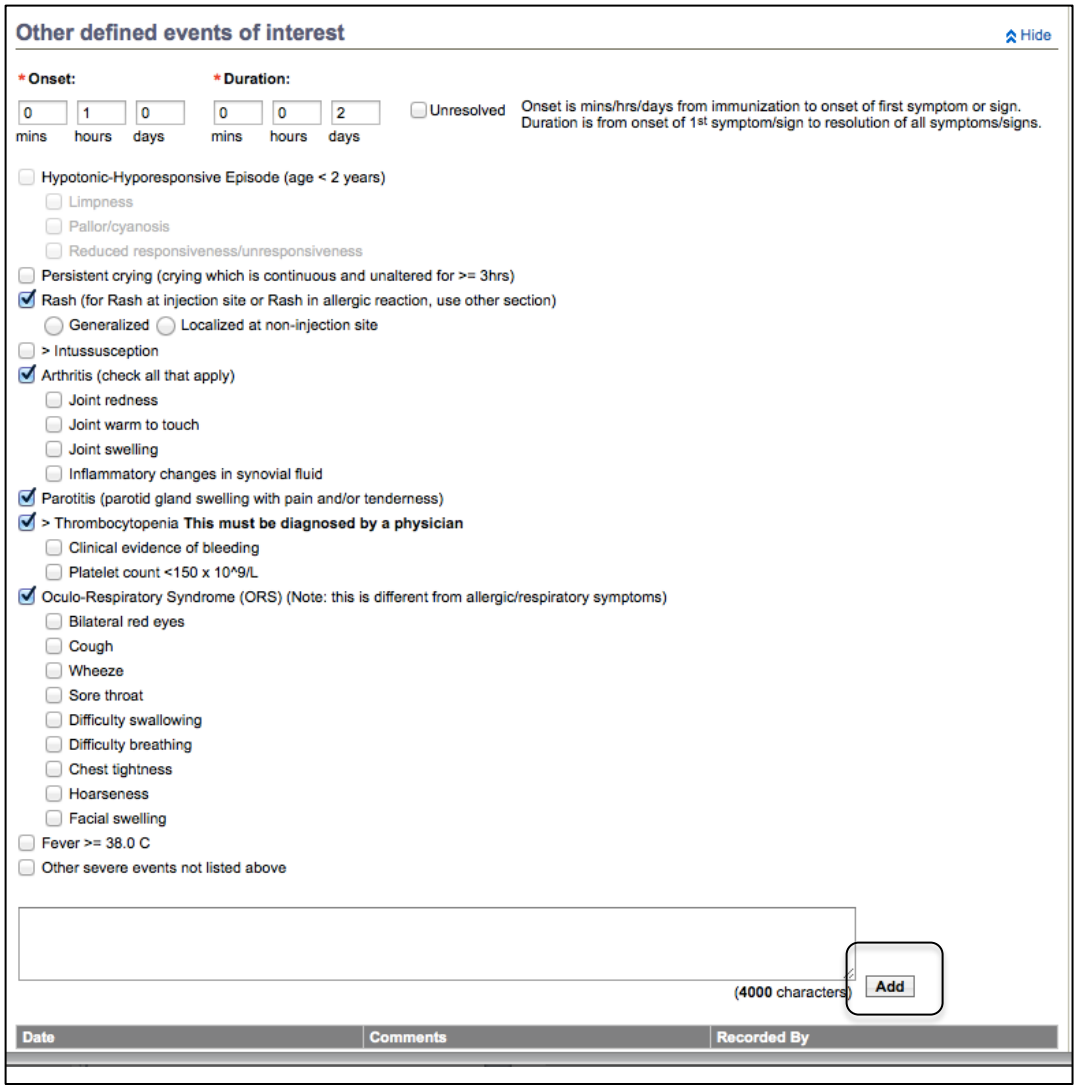
TIP: If the AEFI is related to 'Other defined events of interest', required fields are: **Onset** and **Duration**.



Click on any of the selections related to the "**Other defined events of interest**". Once you click on a sub-section, the descriptive options are available for selection.

Note: The following "**Comments**" should be added to the "**Other defined events of interest**", if applicable:

- Oculo Respiratory Syndrome (ORS) – record Unilateral Red Eyes in the Comment section.



- Thrombocytopenia – record Pettechial Rash in the Comment Section.
- Record Anaesthesia/Parathesia in the Comment Section.

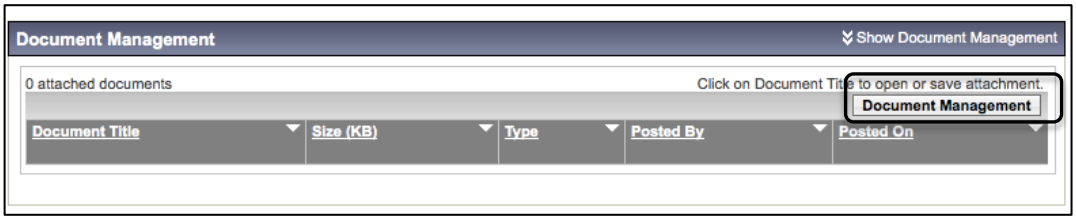
2. Add comments as required, and click **Add** to save the to the Comments Table.

Open up the **Impact of AEFI, Outcome, and level of care** section.

3. Enter related information in the drop-lists. Add any comments, and click **Add** to save the to the Comments Table.

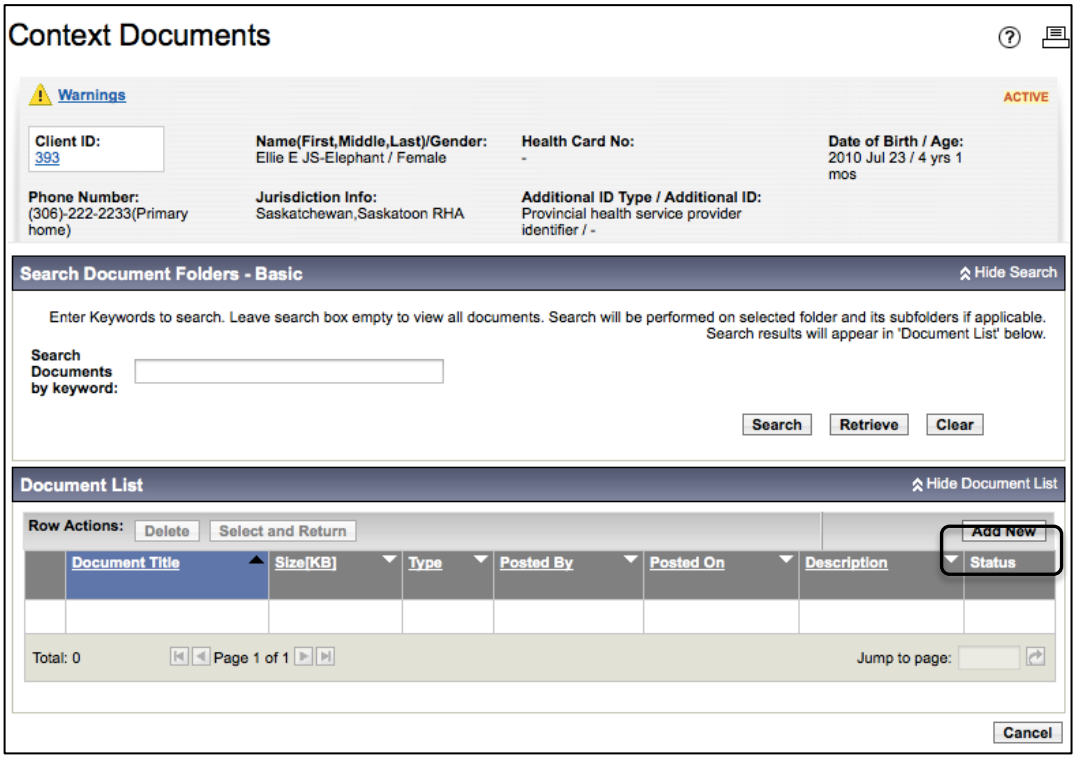
4. Click **Save as Draft** to save information to the AEFI record.

5. Open the **Document Management** section if there are documents to attach to the AEFI Record.



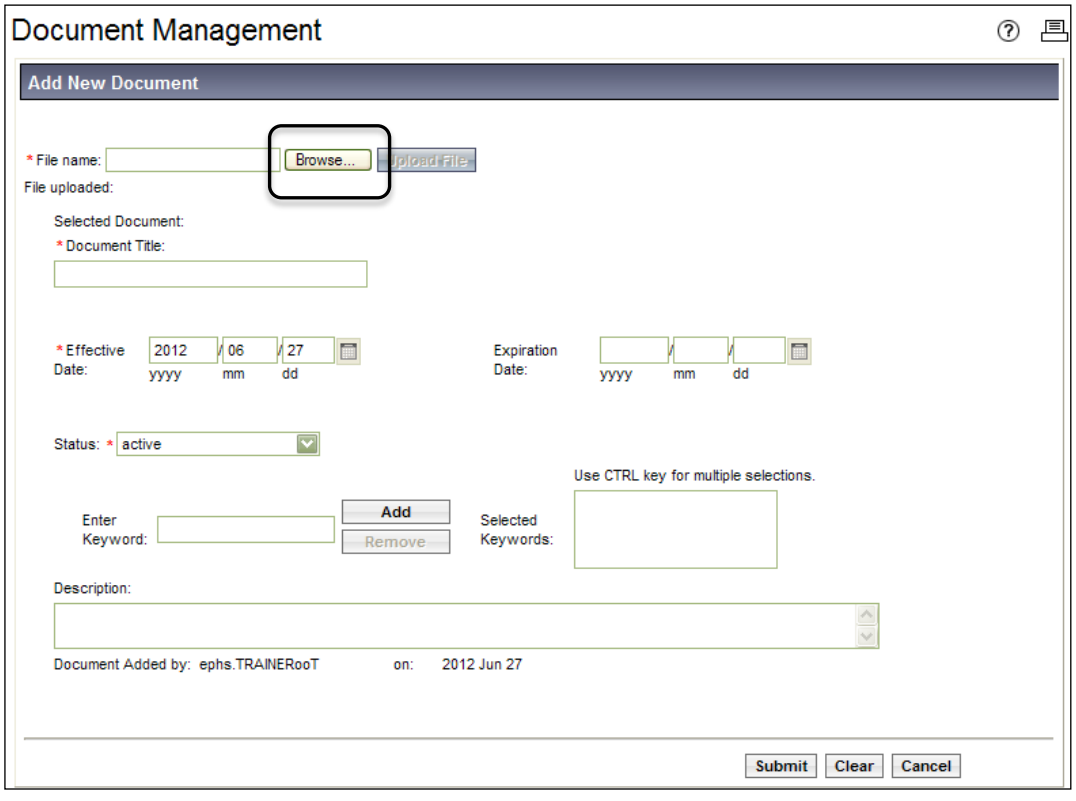
6. Click **Document Management** to attach documents.

The **Context Document** screen displays.



7. Click **Add New**.

The **Document Management** screen displays.

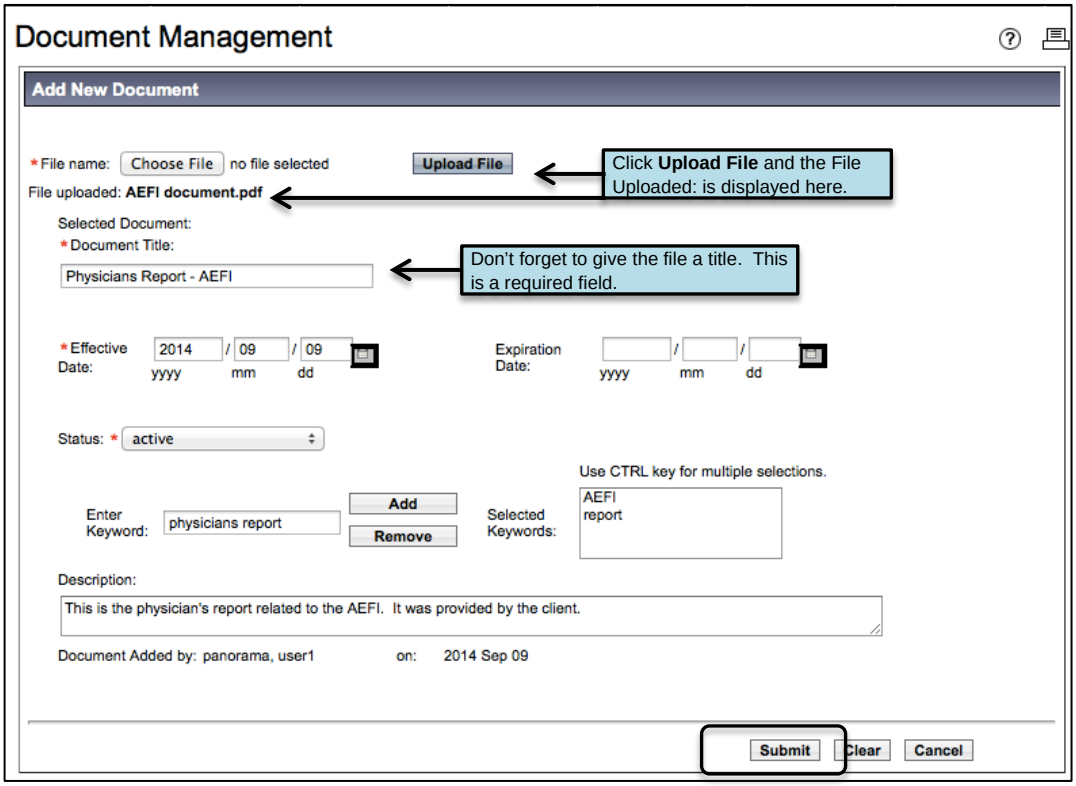


NOTE: The file must be of an acceptable type as per system configuration (e.g. .pdf)

TIP: If you decide to **cancel** the upload, just click Cancel until you return to the **AEFI** screen.

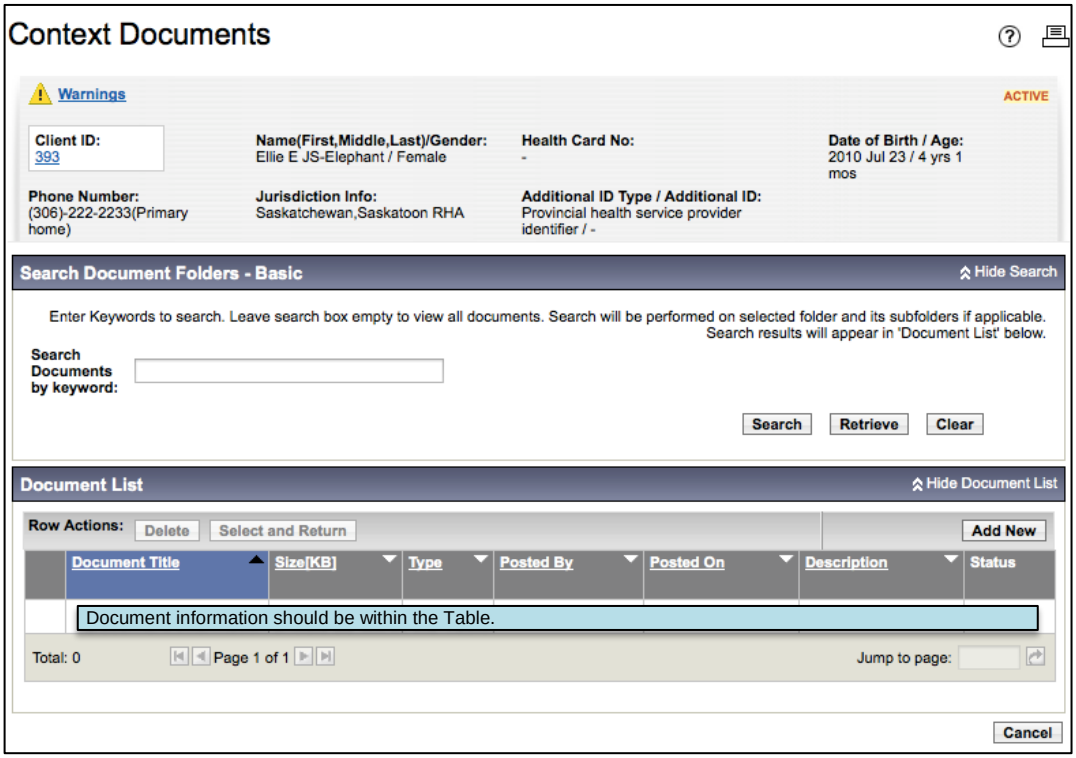
8. Click **Browse** and select the document to be attached from your system. Click **Upload** to upload the file.

9. Fill in required and mandatory fields.



10. Click **Submit**.

The **Context Documents** screen redisplays with the file within the Table.

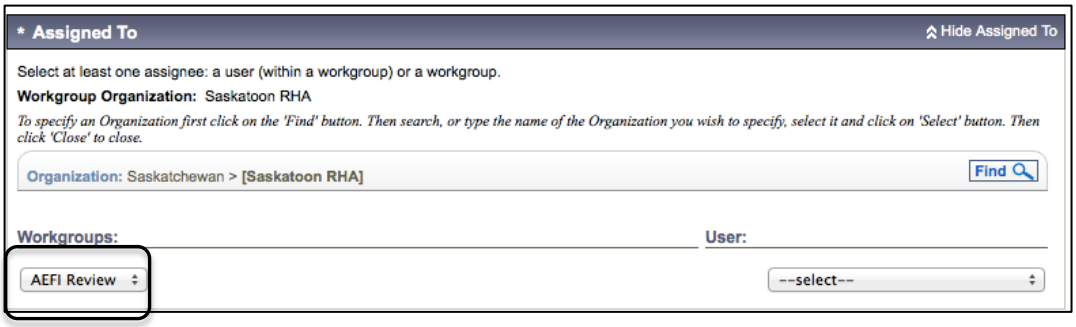


NOTE: The file is not attached in the screenshot as this functionality was currently under configuration at time of user guide development.

11. Click **Cancel** to return to the **Create Adverse Event** screen. Note that the file attached is now seen in the Document Management section of the AEFI Record.

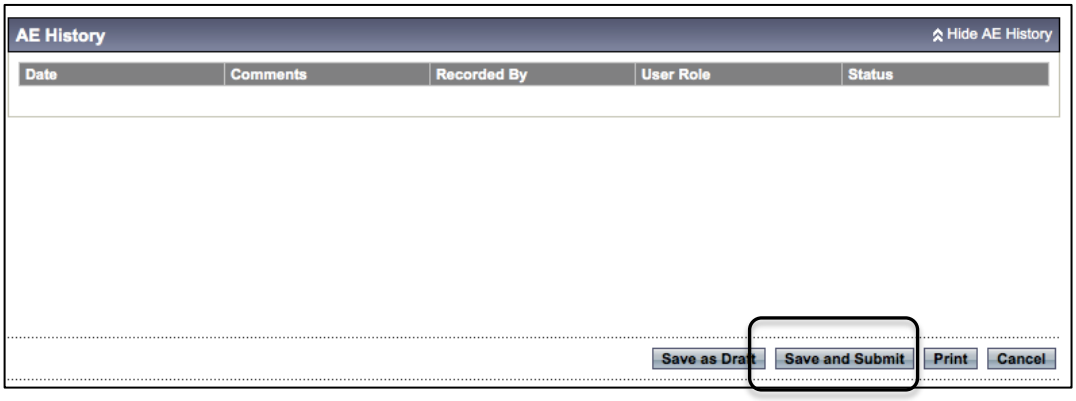
NOTE: The Manager of the Workgroup (e.g. AEFI Review) will receive a Task in Work Management. Tasks are viewed and managed within the **Work Management** module. It is the jurisdiction's prerogative to utilize the **Work Management** module or solely rely on telephone / email communications to notify the reviewer and contributors of the AEFI Report.

12. Open up the **Assigned To** section of the AEFI Record.



13. Select a **Workgroup** from the drop-list. Select an individual **User** from the drop-list if appropriate. This field is mandatory before the user can 'Save and Submit' for review. By sending the notification to the Workgroup, this action changes the status of the AEFI Record to 'Under Review'.

The AE History does not show activity while the AEFI Record is still in 'Draft' mode.

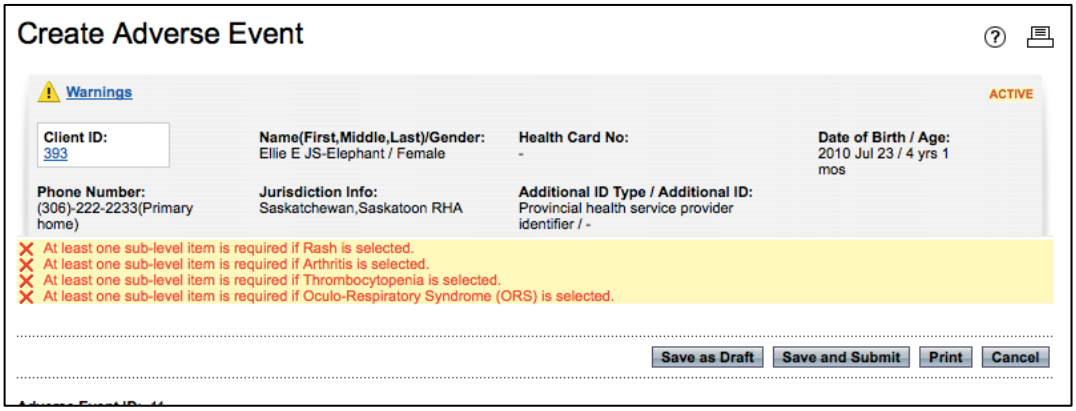


14. When ready to add the recommendations (review process) to the Record, click **Save and Submit**. This is at the bottom and top of the AEFI Record.

Note: there may be some required fields that need to be completed before the Record is saved and submitted. Error messages are displayed on the Header, indicating to the user which fields must be completed. See examples below.

TIP: There are a number of fields within the report that are required, but are not indicated by the *. Depending on the information recorded on the AEFI, certain fields then become mandatory.

TIP: Fix any error messages by updating the AEFI Report, then click 'Save as Draft'. The data must first be saved before it can be submitted.



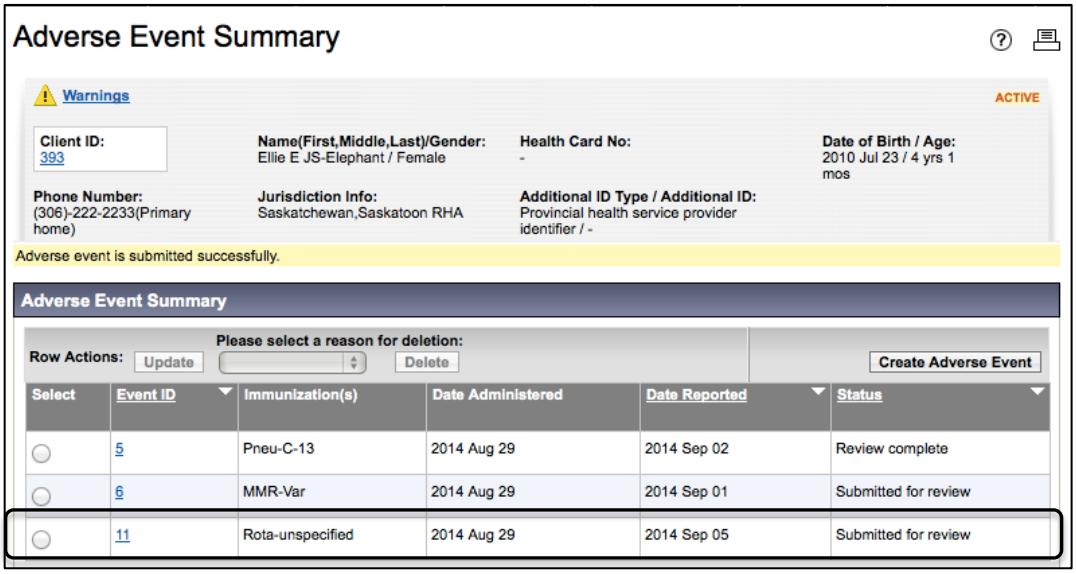
15. Update the AEFI Record as indicated by the X error messages.

16. Click **Save as Draft.** [It is important to first save the information to the Record before it is submitted].

17. Click **Save and Submit**.

The **Adverse Event Summary** screen displays with a message in the Header stating that the Adverse even is submitted successfully.

The status of the AEFI shows "**Submitted for Review**".

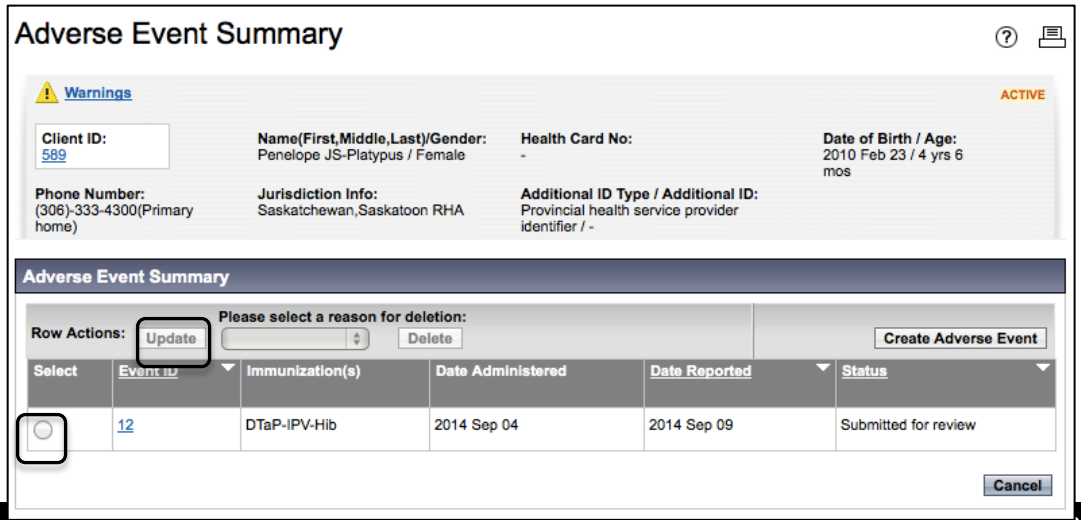


2.0 Adverse Event Review

Once the AEFI Record is submitted for review, a new section is activated within the Record, called **Public Health Recommendations**. This section must be completed in its entirety before the user can complete the AEFI Record. Once the user "Starts Review", the user may "need more information" or "need consultation". See the following sub-section for details relating to this functionality.

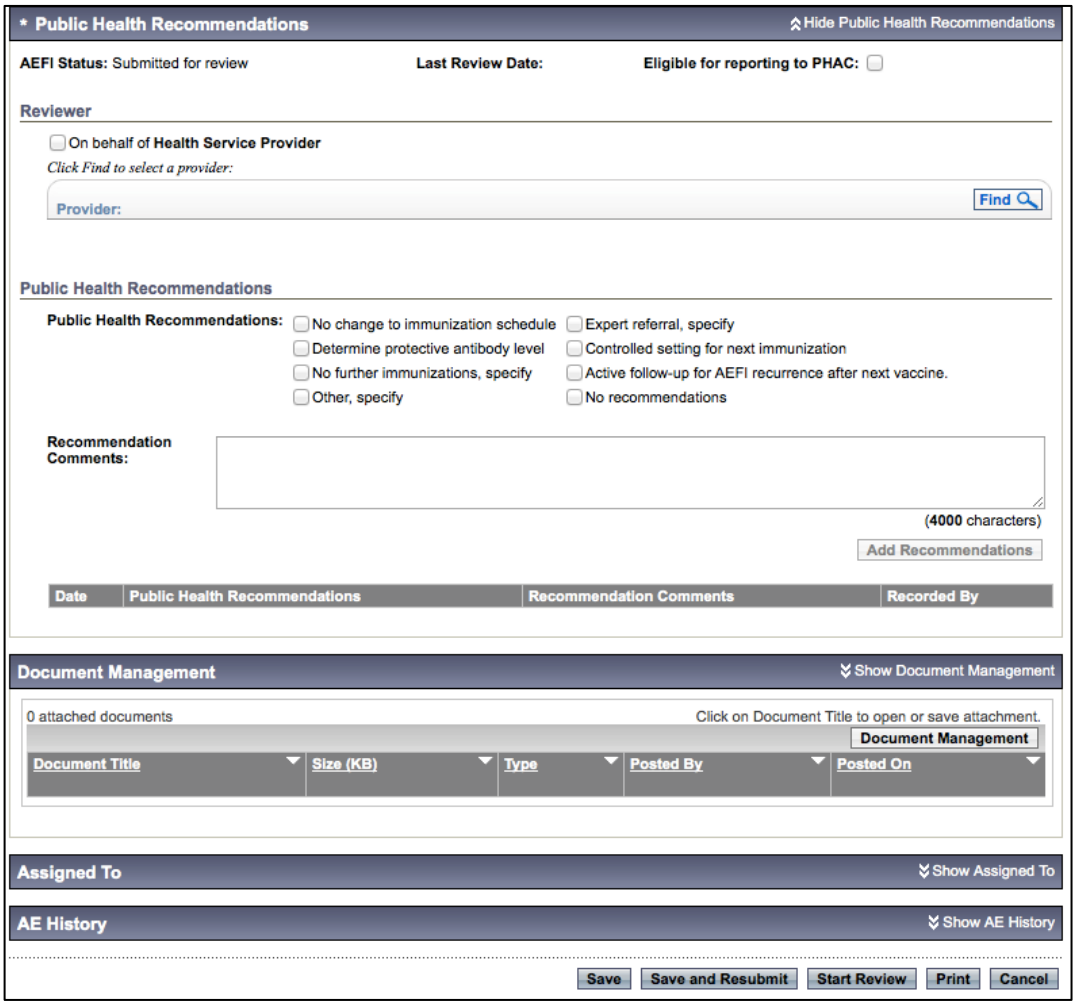
These are steps to take the Record from "Submitted for Review" to "Review Complete".

1. Click Immunizations > Adverse Events (AEFI) from the left navigation bar. The Adverse Event Summary screen displays.



2. Click the radio button beside the AEFI that is “Submitted for Review”, and click **Update**.

The **Create Adverse Event** screen displays. Notice that the screen opens up to the new section, **Public Health Recommendations**.



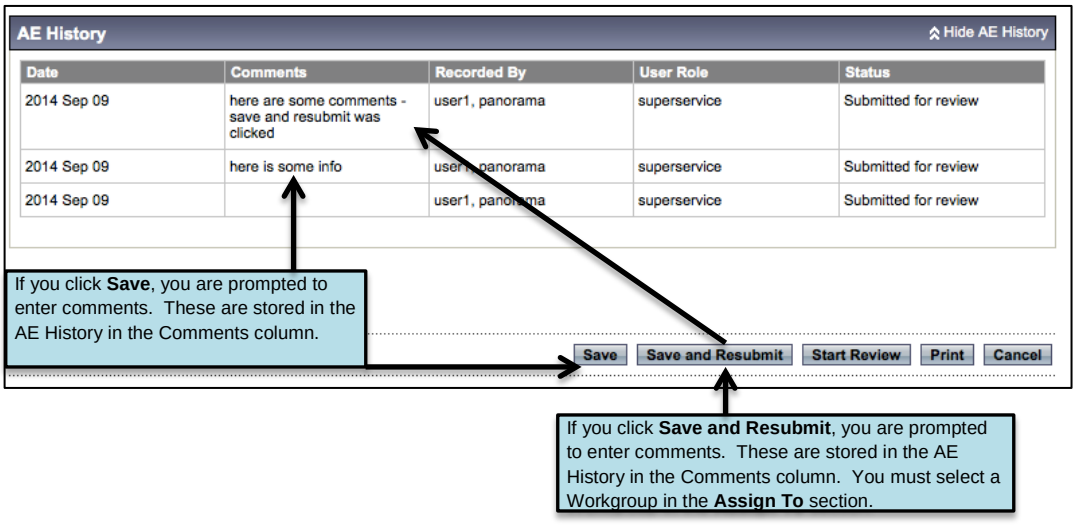
NOTE: The AEFI Report must be “reviewed” in Panorama before it can be complete. It is important for all users to follow Saskatchewan policy and procedure when creating and reviewing an AEFI Report.

Enter the Public Health Recommendations as required.

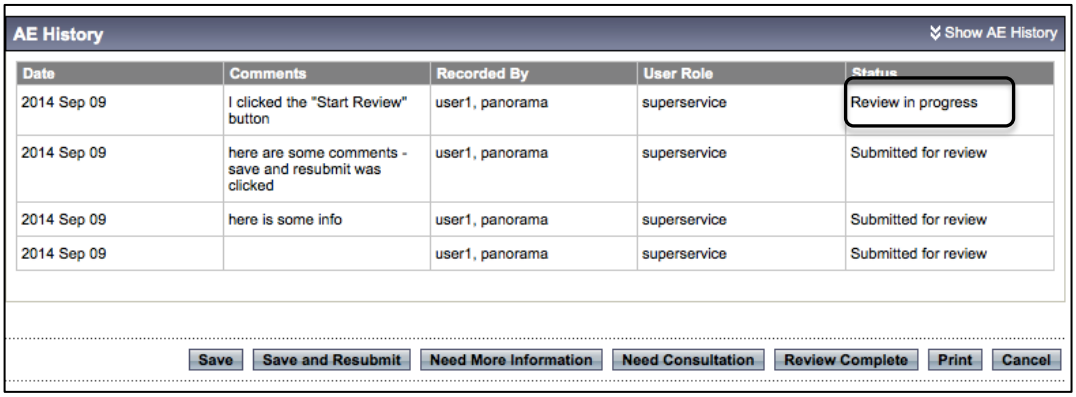
3. Click the checkbox if the AEFI is **Eligible for Reporting to PHAC.**
4. In the Reviewer section, click **Find** to locate the Provider in the Index.
5. Click the checkbox **On behalf Of Health Service Provider**, if the Panorama user is not the Provider.
6. Select the **Public Health Recommendations** applicable to the AEFI.
7. Enter comments in the Recommendations Comments section. Click **Add Recommendations** to add the recommendations to the Table.
8. Add any other information to the AEFI Record as required (see ‘Adverse Event Create’ section for more details).

TIP: To Print the AEFI Report, go to the "Adverse Event Details" screen, and click the Printer icon at the top of the page. For more information, go to the 'View Adverse Event' section of this user guide.

9. Depending on the policy and procedure, the user may choose to **Save, Save and Resubmit**, or **Start Review**.



If the user clicks the **Start Review** button, the user is prompted to add comments. The screen is updated, within the AE History section, the status of the AEFI Record changes to "Review in progress", and new buttons are activated.



Depending on completion of the AEFI Record, the user may choose to complete the Record or indicate that more information or consultation is required.

10. If the documentation is complete, select a Workgroup from the **Assign To** section, and click **Review Complete**. The user is required to enter comments in the text box.

The user is taken to the **Adverse Event Summary** screen, and a message indicates that the Adverse Event was saved successfully.

TIP: If the users are not actively using the Work Management Module (Tasks), then this functionality may still be used in the AEFI report. Notification just needs to be done through email / telephone.

NOTE: Every time the AEFI Report is updated a comment is required. This is meant to track the changes made by the different contributors as audit information if required. It is not displayed from the record.

3.0 Needs More Information / Consultation

The **Need More Information** and **Needs Consultation** functionality may be useful if the people that provide the information or consultation are Panorama users. When these buttons are selected, the user must select that individual or Workgroup in the **Assign To** section. The user(s) are notified through the **Work Management** Module with a Task. This task includes the comments and a hyperlink to the AEFI, so that the user may click directly to the Adverse Event. Once the user accesses the AEFI Record, updates and contributions are made, and then it is re-submitted.

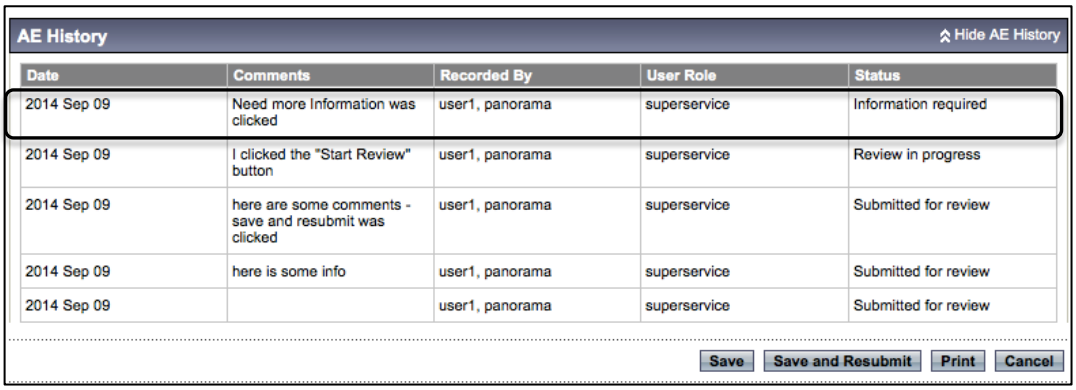
This is the equivalent of passing the AEFI Record to another user to make contributions. Follow these steps for "Need More Information". The "Need Consultation" is the same and therefore not documented in this user guide.

1. While the AEFI Record is in status 'Review in Progress', select a Workgroup / user in the **Assign To** section. Click the **Needs More Information** button. The user is prompted to add comments.

The user is taken to the **Adverse Event Summary** screen, and a message on the Header indicates that the Adverse Event has been updated.

2. The Workgroup /user is notified to make a contribution to the AEFI Record.
3. The user will navigate to the **Adverse Event Summary** screen and click on the radio button beside the adverse event and click **Update**.

The **Create Adverse Event** screen is displayed. At the bottom of the screen, open up and view the **AE History**. The comments and status, etc. are shown.



4. The user makes necessary contributions to the AEFI Record, click **Save**.

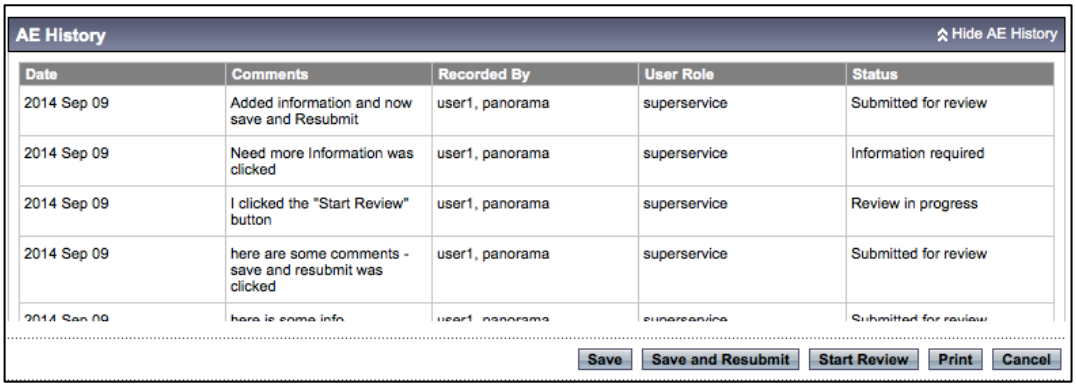
5. Once the user is finished adding the information in the Record, and is ready to submit, navigate to the **Assign To** section and select a Workgroup / user. Click **Save and Resubmit**. The user must add comments in the text field.

The **Adverse Event Summary** is displayed, with a message indicating that the Adverse Event was resubmitted successfully.

The user to whom it is assigned will receive notification to contribute or finish the review of the AEFI Record.

6. This user must once again update the Adverse Event. To do this, navigate to the **Adverse Event Summary** screen and click on the radio button beside the Adverse Event and click **Update**.

The **Create Adverse Event** screen is displayed. At the bottom of the screen, open up and view the **AE History**. The comments and status, etc. are shown.



7. The user may choose to **Start Review**. Comments must be added to the text box.

A message is displayed at the top of the screen indicating that the Adverse Event is under review.

8. Make any changes necessary, then, once complete, select the Workgroup / user in the **Assign To** section, and click **Review Complete**.

E. Delete Adverse Event

An Adverse Event may be deleted if entered in error, a decision was altered, or for another reason. Please be sure to follow Saskatchewan policy and procedures before deleting clinical records.

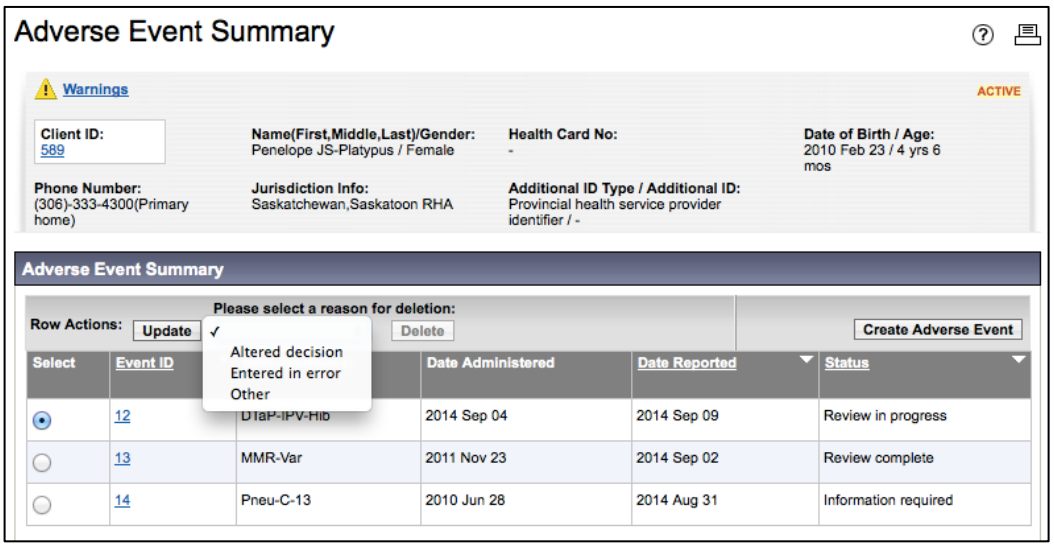
The **Adverse Event Summary** screen contains all of the AEFI Records entered or deleted for the client.

Pre-requisites: The user has successfully logged into Panorama. User is in the Immunization module (tab). Client is in context. An AEFI Record currently exists.

Menu Access: Select Immunizations > Adverse Events (AEFI)

1. Click Immunizations > Adverse Events (AEFI) from the left navigation bar. The Adverse Event Summary screen displays.

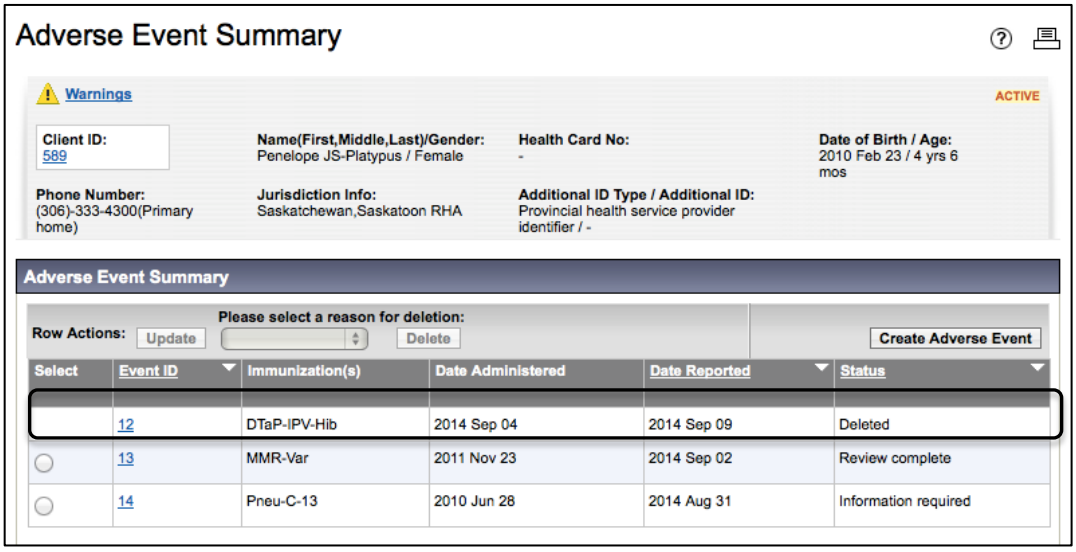
2. To select an existing Adverse Event, click the radio button beside the adverse event to be deleted.



3. Select a reason for deletion. If Reason is **Other**, then add details in the text box that becomes activated.

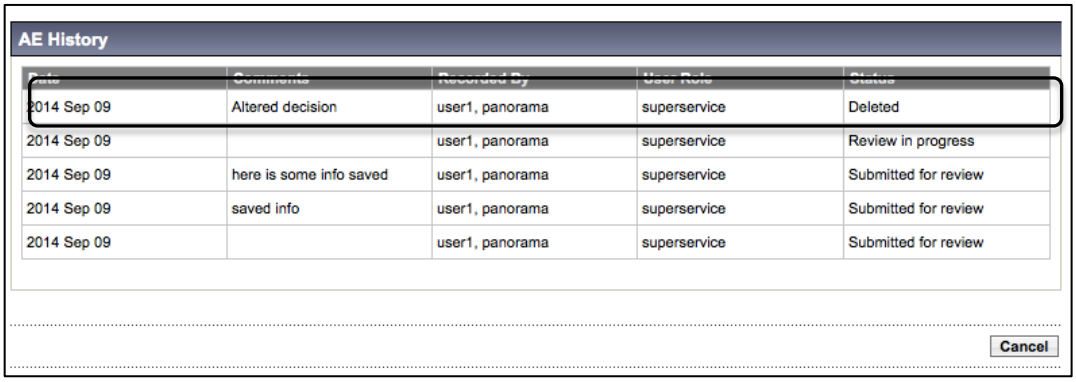
The message displays that the Adverse Event was deleted successfully.

The Adverse Event Summary screen shows the AEFI Record is now deleted, and can no longer be updated (the radio button beside it is removed).



4. To view the Adverse Event, click on the hyperlink.

The **AE History** at the bottom of the Record indicates the reason for deletion.



5. Click **Cancel** to return to the **Adverse Event Summary** screen.