Panorama Guideline

Adverse Events Following Immunization (AEFI)

Please see here for most current version.

Purpose

This guide outlines how to report an Adverse Event Following Immunization (AEFI) in Panorama and is aligned with the Canadian Adverse Events Following Immunization (CAEFISS) User's Guide and the BC Communicable Disease Manual, Chapter 2, Immunization, Part 5 AEFI. It complements the Quick Reference Guide – Immunization, AEFI which provides step-by-step instructions on moving through the Panorama AEFI reporting screens from an information systems perspective.

Health Authority Applicability

Fraser Health, Interior Health, Northern Health, Vancouver Island Health

Practice Level

Public Health Nurses, Communicable Disease Nurse, Medical Health Officers

Developed and maintained by BCCDC:

- Chelsea Treloar, Epidemiologist, Immunization Programs and VPD Service
- With technical support by Trang Dinh , Panorama Central Support Team

Updated August 2017 by BCCDC:

Reviewed and Approved By BCCDC:

- Dr. Monika Naus, Medical Director, Immunization Programs and VPD Service

Related Documents

CD Manual, Chapter 2 Immunization, Part 5: AEFI

References

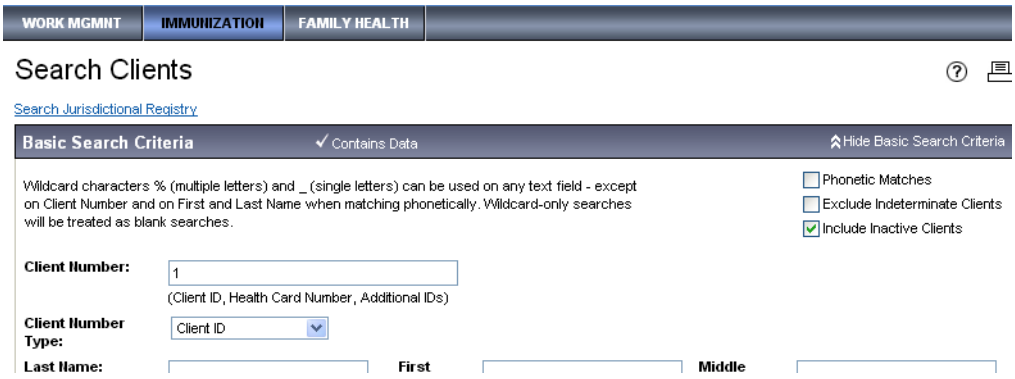
CAEFISS User Guide and CAEFISS Reporting Form

Table of Contents

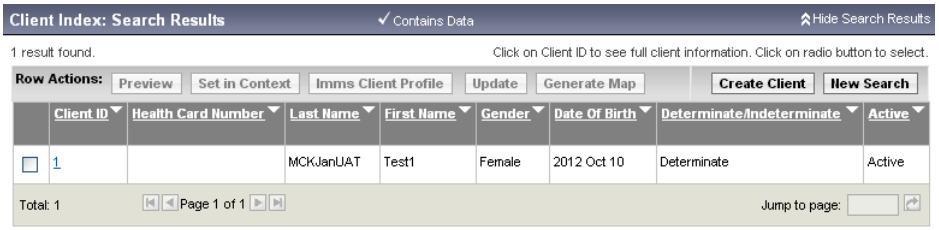
1.0 CLIENT SEARCH

Before entering the AEFI information, the correct client needs to be found first. Follow these steps:

Query and select the client on whom an adverse event has been reported and needs to be recorded in Panorama. Under 'Immunization', enter available client identifiers into the search criteria and select 'Search' at the bottom.



If the client is found, tick the checkbox besides the Client ID and then select "Set in Context" at the top.



Select AEFI under Immunizations in the left sidebar to go to Adverse Event Summary.

If the client is not found, user needs to select "Create Client" to create the client profile. Please refer to the Panorama Immunization Data Entry Guide on how to create a client profile.

The term 'report' is used in this guideline to mean the record related to the AEFI associated with a particular vaccine or set of vaccines/ immunizing agents/ product(s) administered at a particular appointment. It may be considered a clinical record or a report of an AEFI, and has been designed to map to the CAEFISS AEFI Reporting Form.

2.0 ADVERSE EVENT SUMMARY

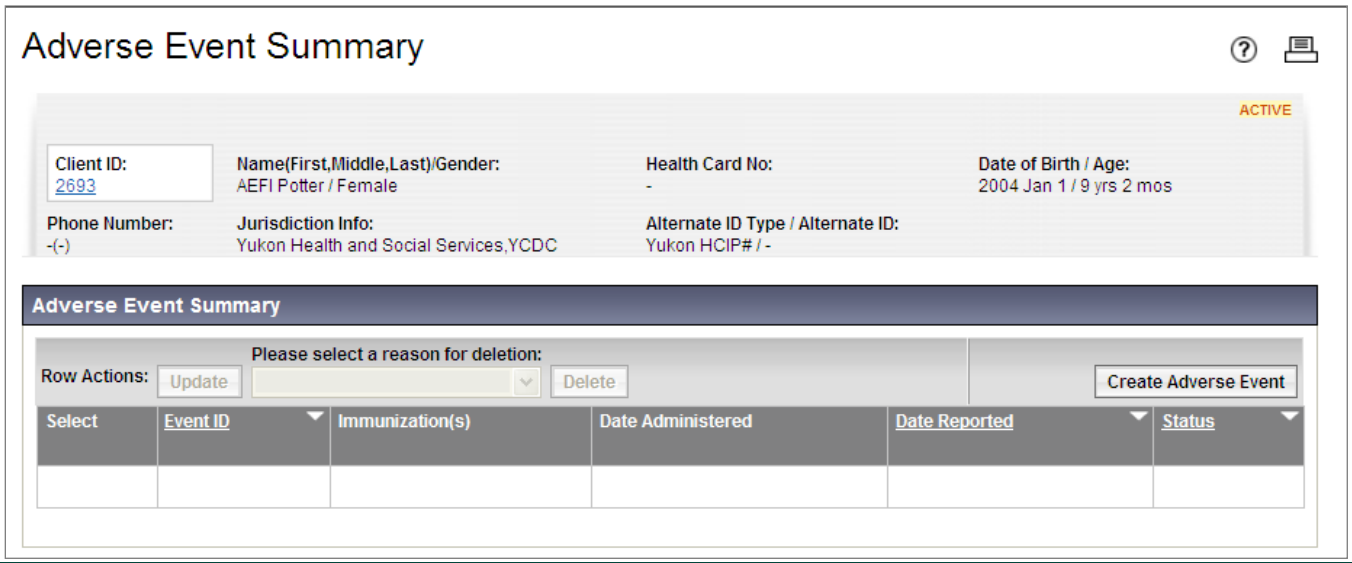
The Adverse Event Summary contains all the AEFI reports that have been entered or deleted for the client set in context. Before proceeding to enter a new AEFI report, the **user must first check the client's immunization history in 'Immunization' for the immunization record associated with the new AEFI.** If the immunization record has not been entered in Panorama, you will first need to create it.

Adverse events associated with non-vaccine pharmaceuticals: The Panorama AEFI module has been designed specifically for recording and reporting of adverse events following receipt of vaccines (active immunizing agents) to the province and the national Canadian Adverse Event Following Immunization Surveillance System (CAEFISS), Public Health Agency of Canada. Adverse events related to passive immunizing agents (immunoglobulins) and TB skin tests (Tuberculin Purified Protein Derivative – Mantoux - Tubersol™) can be recorded in Panorama, but such recording will not result in reporting of these events to the appropriate federal authorities. Adverse events following immunoglobulins and TB skin tests should be reported to the Marketed Health Products Directorate (MHPD) of Health Canada by the health care provider using the 'Side Effect Reporting Form' or through online or telephone means as outlined here.

Recording adverse events as part of the patient's clinical record can be done for a) immunoglobulins in the Panorama AEFI module, with the immunoglobulin recorded as an 'agent' in the immunization module, and b) TB skin tests in the Panorama TB module.

If an adverse event occurs in an individual who received both vaccine and a passive immunizing agent or TB skin test, and the health care provider is uncertain about which product was causally associated with the event, the event should be reported both as a vaccine-related AEFI through Panorama, and as an immunoglobulin or TB skin test related event to MHPD at outlined above. In the Panorama AEFI module, details of the TB skin test should be entered as a concomitant medication(s) (see items #16 and 17 in Section 7 of this document).

To create a new adverse event report, click on 'Create Adverse Event'.



3.0 OVERVIEW OF THE ADVERSE EVENT REPORT

Recorder completes the data elements on the Panorama AEFI Report:

- Reporting Source
- Immunization Data
- Information at Time of Immunization and AEFI Onset
- AEFI Details
- Impact of AEFI, Outcome and level of care
- Document Management (**this section displays upon saving the form as draft)**
- Assigned To

Submit for review

Need consultation notes

Need more information

Reviewer requests for additional information or consultation

Reviewer completes

- Public Health Recommendations (**this section displays upon receiving a submitted form for review)**
- Change to update report as required

Review Complete

The AEFI report is a multi-section electronic record. Each section can be expanded to fill the corresponding information. It does not need to be completed in a specific order. Follow the rest of the guideline to complete the report and review process.

3.1 Critical Points to Consider:

SAVE AS DRAFT: You can save the data you have entered at any point by clicking **Save as Draft**. However, you must first enter the following information: reporter (by default it will be the logged in user) and one associated immunization.

SAVE AND SUBMIT: Before an AEFI report can be submitted for review, the system requires the following information:

- Reporting Source (Section 5)
    - Source of Information
- Information at Time of Immunization and AEFI Onset (Section 7)
    - Whether client has history of AEFI following prior dose of the same vaccine
    - Whether AEFI was associated with a known immunization incident (error)
- AEFI Details (Section 8)
    - Reaction's onset and duration values have been entered
- Assigned To (Section 10)
    - Workgroup (can specify Panorama User in the list)

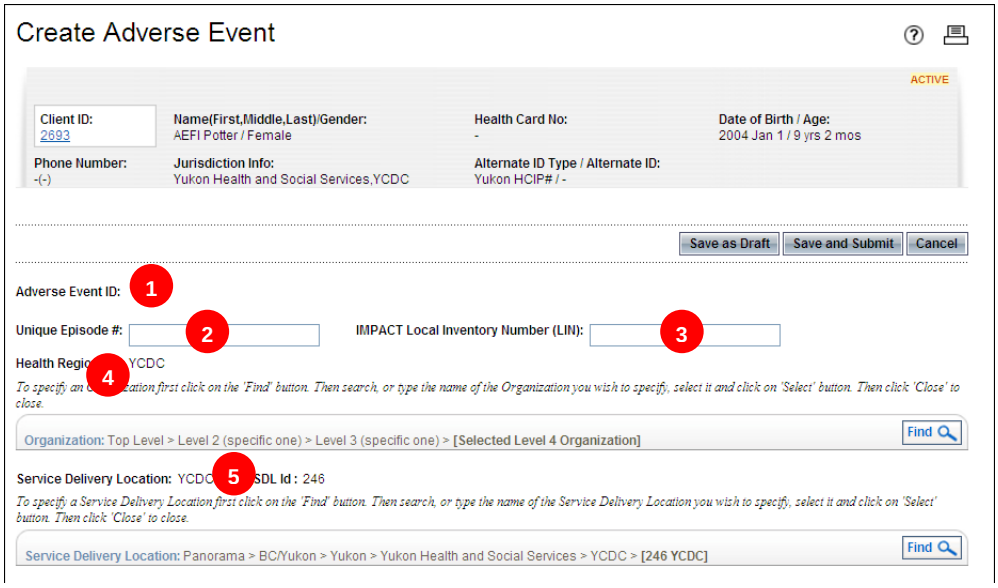
UPDATE: Only Panorama users with permissions to 'write' can update the report. Once submitted, this can be done by selecting the desired AEFI report and clicking 'Update' in the Adverse Event Summary. After each update, user needs to record what has been updated in the corresponding comment field if available. See **Section 13** for more information.

DELETE: Only Panorama users with permission to 'delete' can delete the report. Submitted AEFI form can be deleted by selecting the desired AEFI report and select 'Delete' in the Adverse Event Summary. User must select reason for deletion (Does not meet temporal criteria, Entered in error, Other). If 'Other' is selected, user needs to specify the 'other' reason in the textbox.

COMMENT fields: Each section contains a section –specific comment field; these appear at the bottom of the section as an empty box with '(4000 characters)' at the bottom right, indicating that the maximum length of text including spaces entered into each of these fields is 4000 characters. As you type content, the number of characters remaining will count down. The 'Add' button must be clicked after typing text into the comment field in order to have the comment saved. Once that comment is saved, you can create a second/ third/ etc. comment in the same section each time using another 4000-character field. Use the field related to the category of the adverse event to record additional comments related to that event type; that is, for neurologic events, use the comments field in the neurologic section to enter additional information related to the neurologic event(s). When 'Add' is clicked the comment will appear as a 'frozen' note in the area immediately below and the comment cannot be edited or deleted without also deleting the entire report. Do not enter AEFI-related comments into Client's Notes.

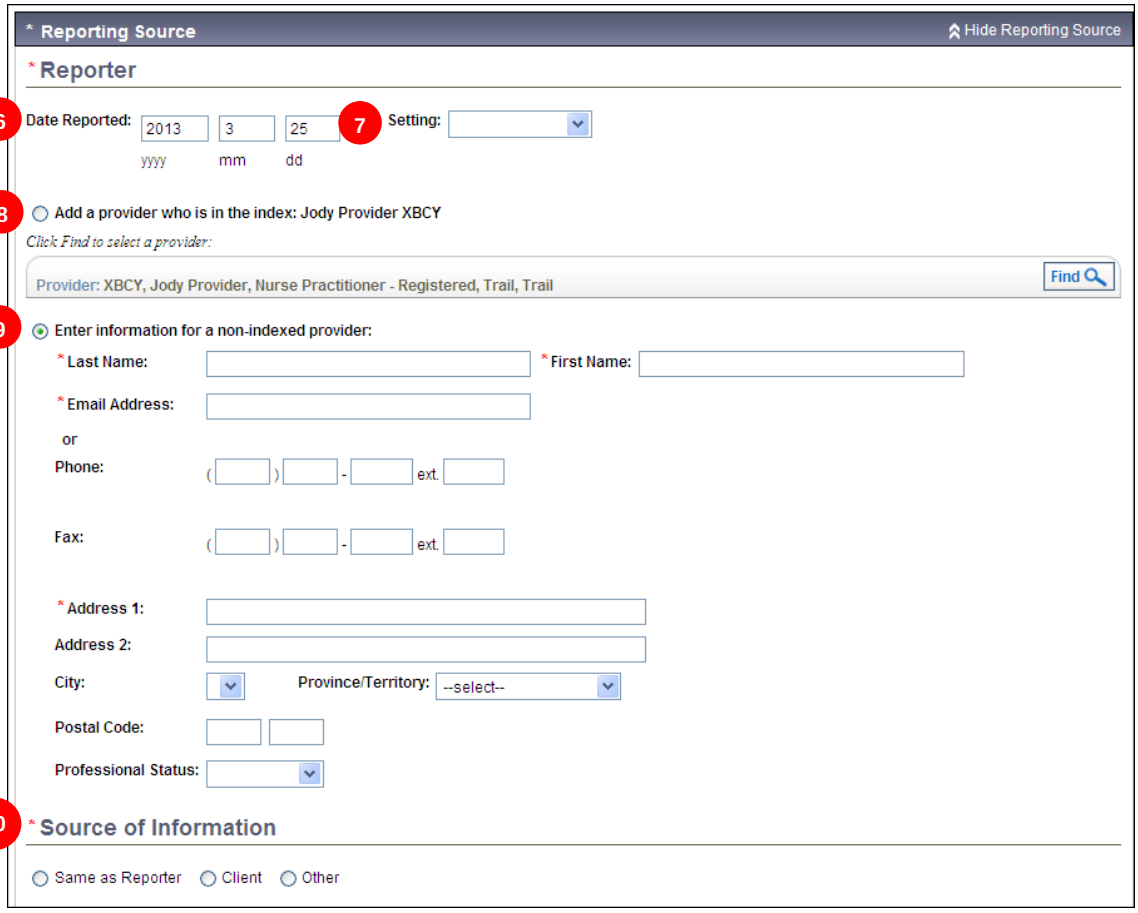
NOTE: Additional information should always be added in one of the comment fields. In particular, updates to follow-up should be added as a comment under 9.0 Impact of AEFI, Outcome and level of care. Adding AEFI related information in 'Notes' or 'Encounter Details' in Panorama is not recommended. Although details under 'Notes' or 'Encounter Details' will be linked to the AEFI, the AEFI report will not display these when viewed. User can only view these under 'Notes' and 'Encounter Details'.

4.0 GENERAL FIELDS



General Fields			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
1.	Adverse Event ID	Unique identifier. System-generated	
2.	Unique Episode #	Already captured by 'Adverse Event ID', see above.	Leave it blank
3.	IMPACT Local Inventory Number (LIN)	Unique identifier assigned to a client identified as an AEFI through the BC Children's Hospital IMPACT site	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.
4.	Health Region	Branch office of the Panorama user logged-in user	By default, the value in this field is the branch office corresponding to that of the logged-in Panorama user. This item is the same as the 'responsible health unit' in iPHIS. The branch office selected should be the branch office responsible for the management/ follow up and reporting of the adverse event. This will usually correspond with the branch office associated with the address of residence of the client. The branch office should be changed from the default selection only if the logged in user is doing the data entry on behalf of a responsible branch office that differs from their own branch office. To change this field, select 'Find' and enter the correct branch office. This is a type forward selection process i.e., not a drop-down list but branch names beginning with the letters you type will show up.
5.	Service Delivery Location	Branch office of the of the Panorama user logged-in.	Same as for #4.

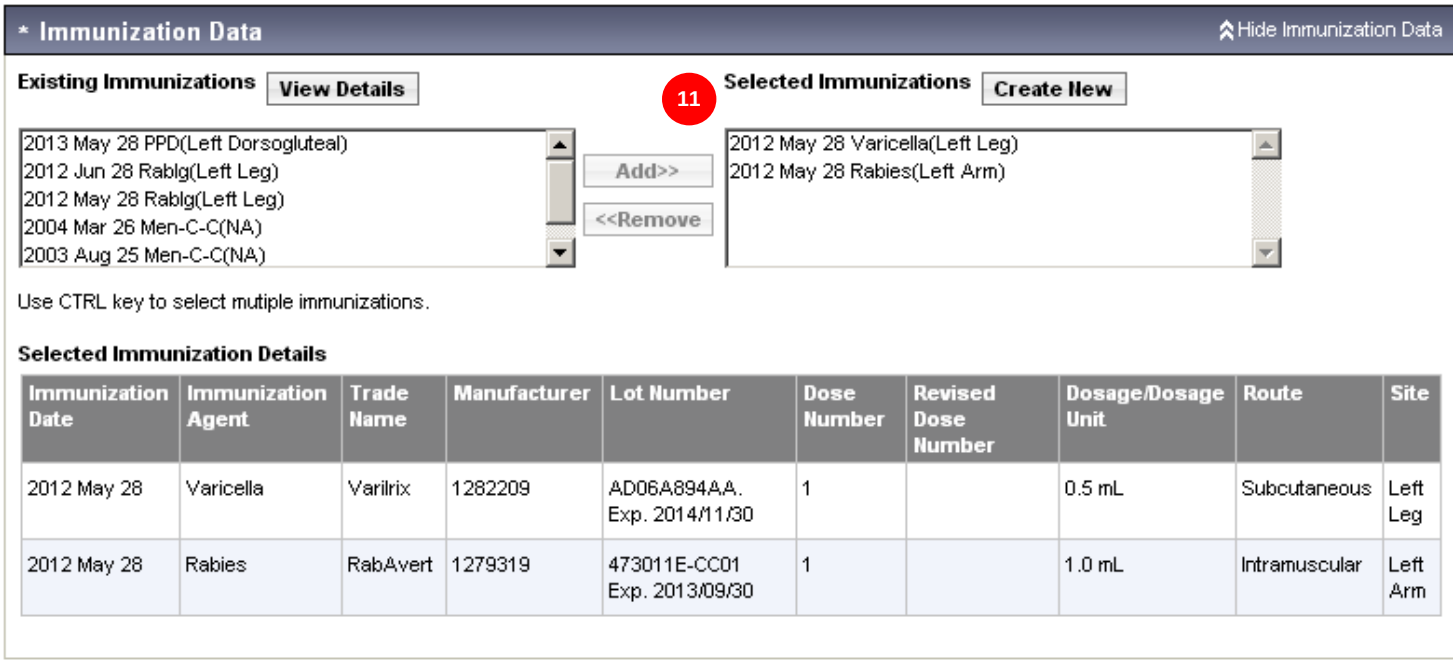
5.0 REPORTING SOURCE



Reporting Source			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
6.	Reporter - Date Reported	Date on which the adverse event was reported to the health authority.	Date Reported defaults to the date when report is created. If the AEFI information has been reported before the current date, then record the earlier date. If this date is before immunization date, a logic error will appear and it cannot be entered.
7.	Reporter - Setting	Setting in which the reporter is employed.	Reporter is the health care provider who received and reported the AEFI information to the health unit. This person may not be the user who enters the information in Panorama. This field is optional. Select the most appropriate option: **Valid values:** • Physician Office • Public Health • Hospital • Other If 'Other' is selected, must specify in the pop-up textbox.

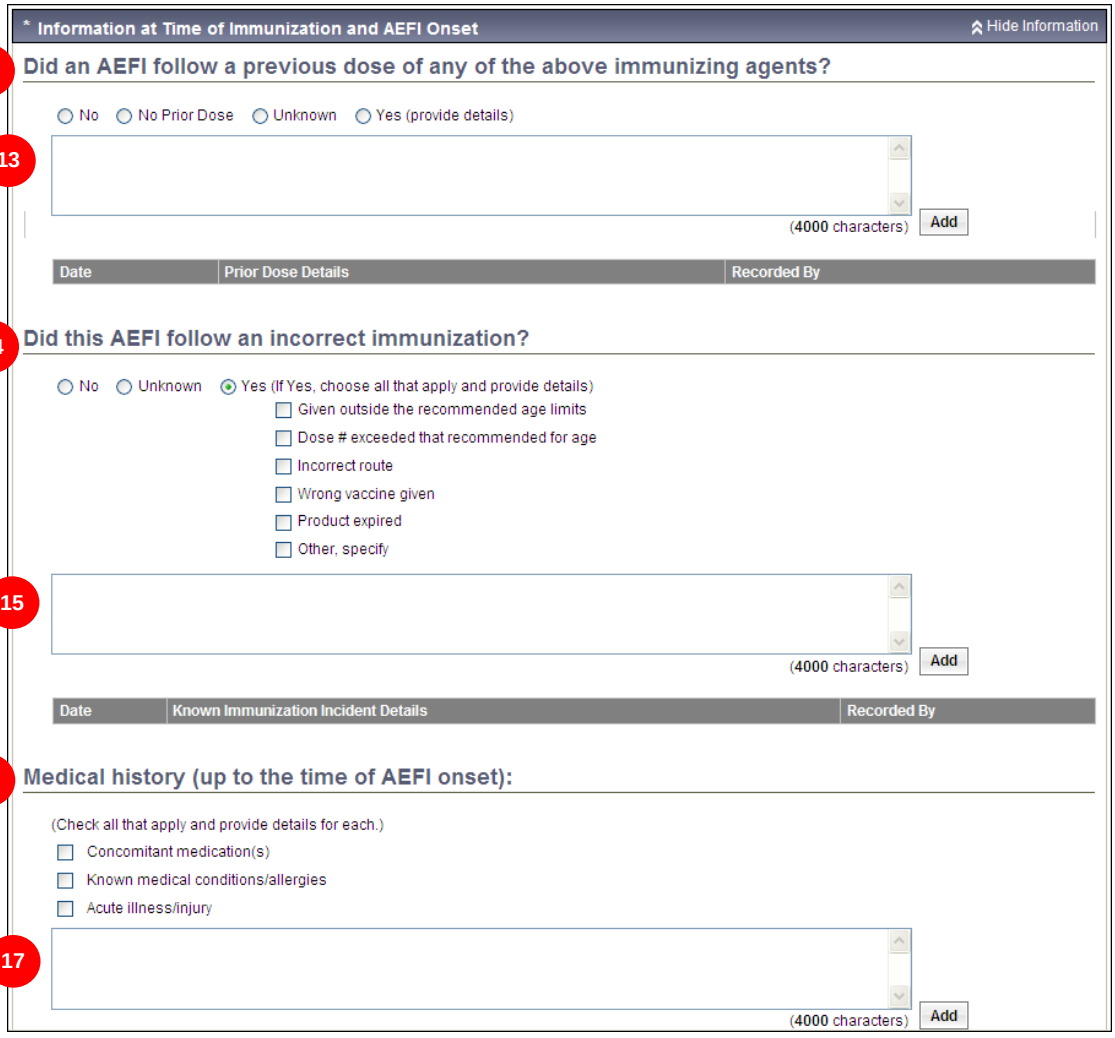
Reporting Source			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
8.	Reporter - Provider (in Index)	Name and title of the reporter.	Reporter is the health care provider who received and reported the AEFI information to the health unit. This person may not be the user who enters the information in Panorama. Defaults to the logged in user. To change, select 'Find' and search by last name. Only indexed (recorded in Panorama) providers will be shown.
9.	Reporter - Information for a non-indexed provider	Name and title of the reporter.	If the reporter is not indexed, identification information must be provided here. When the field is selected, the lower level fields will be enabled. Proceed to complete the prompted fields.
10.	Source of Information	Who provided the AEFI information	Source of information can be the client, the immunizer (PHN, physician, pharmacist), or a secondary source such as parent of a child recipient. Defaults to the logged in user. To change, select Client or Other. **Valid values:** • Same as reporter • Client • Other If 'Other' is selected, demographic and identification questions will be asked (name, email, and address are required questions).

6.0 IMMUNIZATION DATA



Immunization Data			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
11.	Selected Immunizations	Vaccines or immunizing agent(s) agents suspected to be associated with the event.	This is a multiple response item and more than one agent can be selected from the 'Existing Immunizations" list of agents. All of the Existing Immunizations given at the same appointment may be associated to the reported event(s). If it was a local reaction at the site where only 1 or 2 vaccines were given, select the appropriate agent(s) accordingly. If the client had a systemic reaction and a specific vaccine cannot be definitively associated with the event, then all vaccines administered at that appointment should be selected (even if client also had a local reaction associated with only one of the vaccines). Once an agent has been selected from the Existing Immunizations list and an AEFI report on that product given on that date created, a second AEFI report on that same agent/date combination cannot be made. All AEFIs associated with that agent/ date combination must be entered in the same AEFI report. Adverse events following non-vaccines (e.g., immunoglobulins) may be recorded through this feature. Adverse events following non-vaccines should also be reported to Health Canada Marketed Health Products Directorate as required for drug reaction reporting as outlined at this site: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html See section 2.0.

7.0 INFORMATION AT TIME OF IMMUNIZATION AND AEFI ONSET



Information at Time of Immunization and AEFI Onset			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
12.	Did an AEFI follow a previous dose of any of the above immunizing agents?	History of AEFI associated with the same vaccine(s) selected in No.11	This is a mandatory question before submission. Select one of the following: **Valid Values:** • No • No Prior Dose • Unknown • Yes (provide details) If 'Yes' is selected, user must enter additional information in the 'Comments' field before the form can be submitted. See below (No.13).

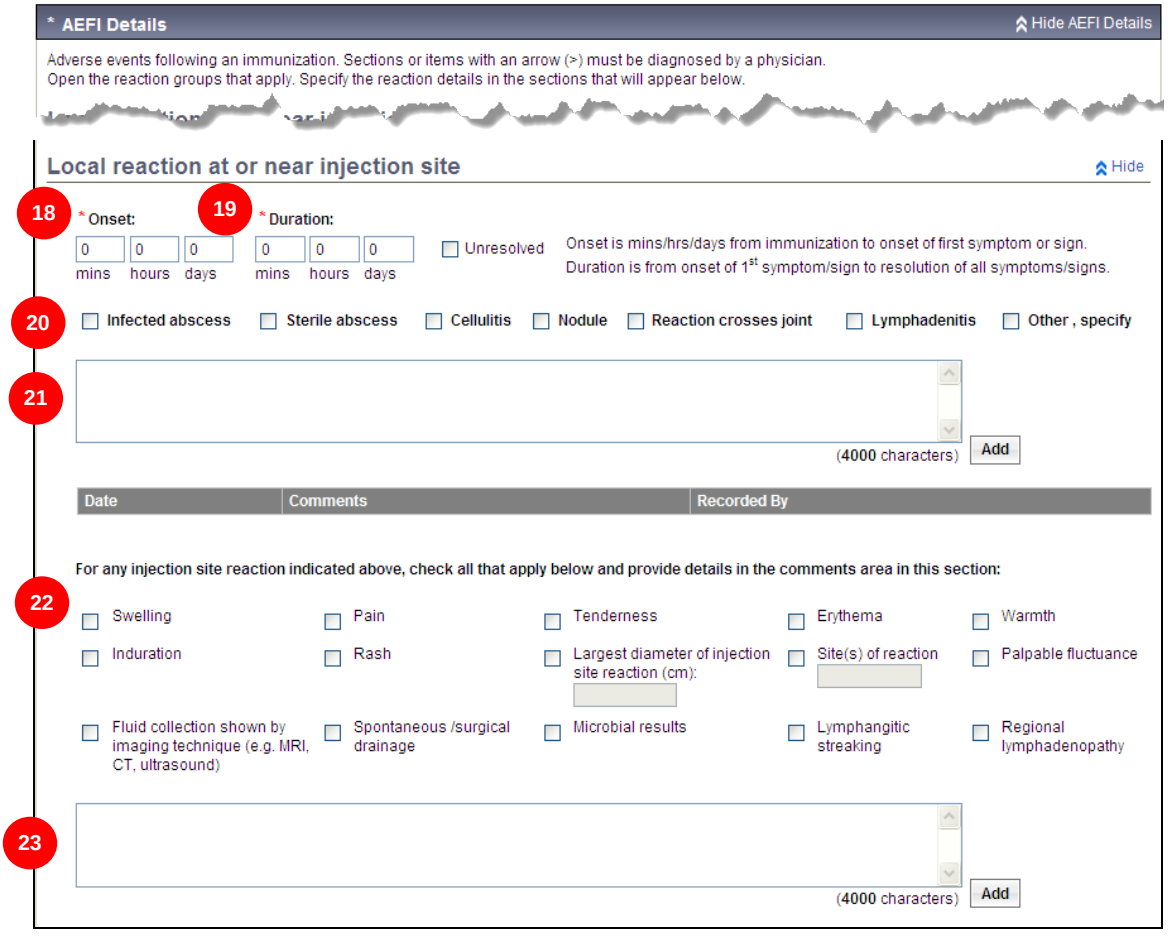
Information at Time of Immunization and AEFI Onset			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
13.	Comments for No.12	Description of the AEFI following the previous dose	Mandatory if Yes is selected for question No.12. Enter time to onset and duration, AEFI details, severity of AEFI, whether event was less or more severe than the event following the current dose, dose number, and date of vaccination. If a comment is recorded, record the Valid Value which it accompanies, e.g. "Yes. The prior event following this vaccine consisted of…." Once comment is added, it cannot be updated or deleted.
14.	Did this AEFI follow an incorrect immunization?	Describe if there was a vaccination error associated with the event	This is a mandatory question before submission. **Valid Values:** • No • Unknown • Yes If 'Yes' is selected, user must choose at least one of the lower level options. **If Yes:** • Given outside the recommended age limits (vaccine was administered to an individual who was not within the recommended age limits for a specific vaccine) • Dose # exceeded that recommended for age (larger dose of vaccine was administered than is recommended for the patient's age group) • Incorrect route (vaccine was administered via a route not recommended for its administration such as SC vs. IM) • Wrong vaccine given (unintended vaccine was administered) • Product expired (vaccine was administered after the expiry date as indicated on the vaccine label by the manufacturer and/or after the recommended amount of time elapsed between the first use of a multi-dose vial and the last use) • Other, specify (error has occurred that is not accurately reflected in the list of provided errors) If 'Other' is selected, user must enter additional details in the Comments field before submitting the report. See below (No.15).
15.	Comments for No.14	Description specifying the vaccination error selected in No.14	Mandatory if 'Other, specify' is selected for question No.14 Once comment is added, it cannot be updated or deleted.

Information at Time of Immunization and AEFI Onset			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
16.	Medical history (up to the time of AEFI onset)	Any medical or medication history before AEFI onset	**Valid Values:** • Concomitant medication(s) • Known medical conditions/allergies • Acute illness/injury If any of the above options is selected, must provide the details in comments, see below (No.17). If there is no medical history (e.g., underlying medical conditions) relevant to this event, enter "No medical history found" in comments (No. 17).
17.	Comments for No.16	Description of the medical or medication history	Mandatory if any option is selected for question No.16. <u>Concomitant medication(s)</u> Provide name of all medications, including prescription, over the counter and herbal supplements, which the client had been taking immediately prior to the time of AEFI onset. When available, provide the dose, frequency, route of administration and reason for taking each concomitant medication. If a TB skin test was administered at the same visit enter the details of the TB skin test, including lot number when available, here. <u>Known medical conditions/allergies</u> Indicate all known medical conditions and/or allergies, including pregnancy, that the client experienced prior to the time of immunization with a corresponding date/month/or year of onset. Include any conditions for which the client is taking a concomitant medication including chronic conditions with intermittent symptoms such as migraine headaches. <u>Acute illness/injury</u> Indicate if client had an acute illness and/or injury immediately prior to the time of immunization and specify a corresponding date/month/or year of onset If none of the options in No.16 is selected but medical history is found, please enter any other information relevant to client's medical history, including AEFI following other vaccines and relevant medical family history. If there is NO medical history, enter "No medical history found" in comments. Once comment is added, it cannot be updated or deleted.

8.0 AEFI DETAILS

AEFI details and classifications are reported in this section, which has 4 sub-sections. **At least one sub-section must be completed before submission.** Indicate the details of the AEFI being reported by checking all that apply, note that multiple sub-sections can be completed should there be several reactions following an immunization. **High level definitions have been provided for most events listed in this section and in the CAEFISS User Guide Section 9 – AEFI Details**. Certain event categories must also be diagnosed by a physician. For more in depth information around Clinical Management Guidelines, please refer to the Immunization Program Manual, Part 5 – Adverse Events Following Immunization, available on the BC CDC website.

8.1 Local Reaction At or Near Injection Site



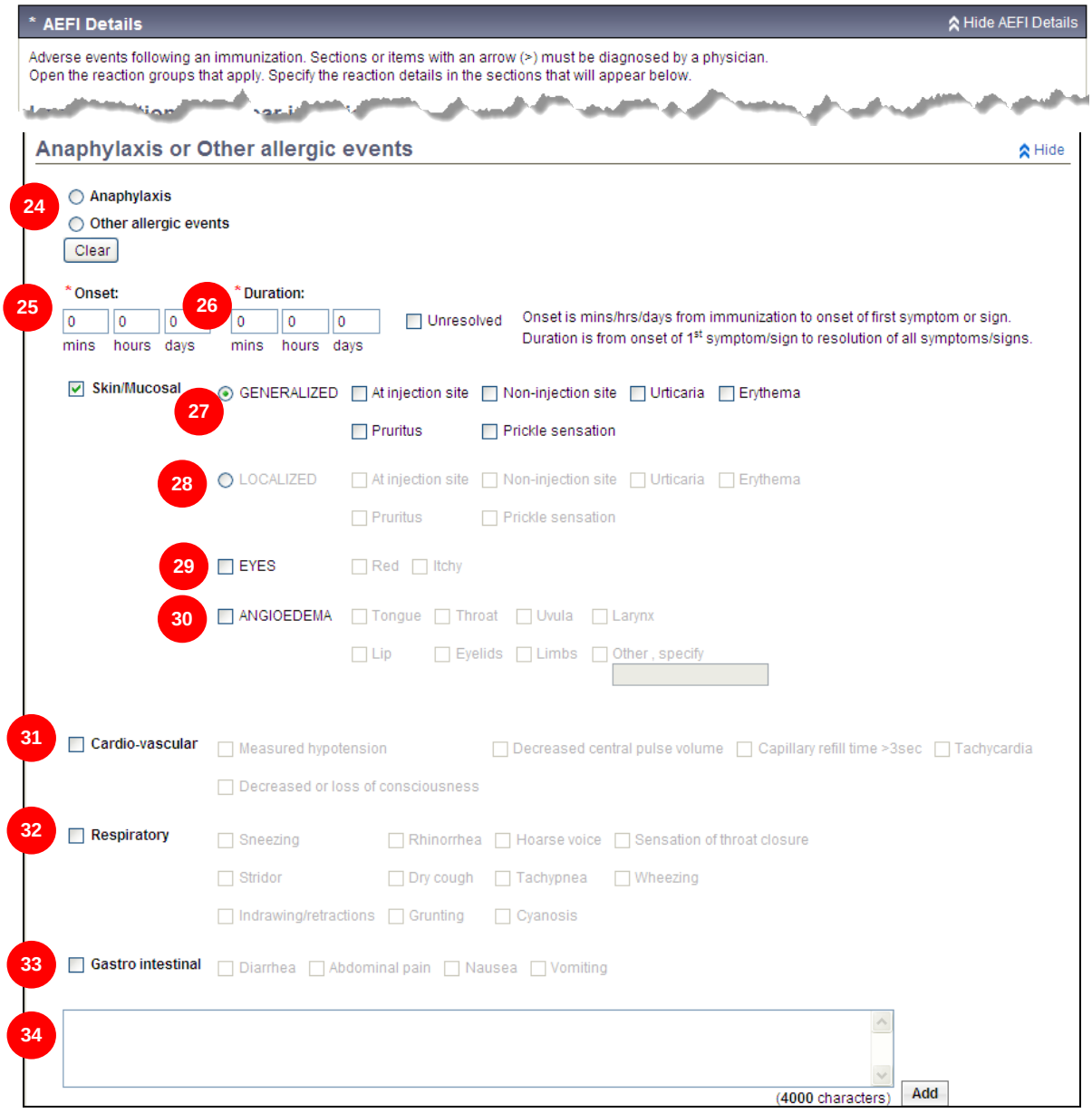
Local reaction at or near injection site			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
If the local reaction is allergic in nature, do not record it here. Record it instead under Section: Anaphylaxis and Other allergic events.			
18.	Onset	Interval of time between the administrations of the vaccine(s) associated with the event and the onset of the first symptoms or signs of the event.	Mandatory field if event falls under this section. Record minute or hour or day parameter. It is not necessary to record more than one time parameter. Record minutes if event onset < 1 hour post-vaccination, hours if event onset < 24 hours post-vaccination, and days if event onset 1 or more days post-vaccination. If hours or days are recorded, record the number of **complete** hours or days between vaccine administration and onset of event.
19.	Duration	Interval of time from the onset of the first symptom until the symptom was resolved.	Mandatory field if event falls under this section and has resolved. If unresolved, leave this blank and must check 'Unresolved' on the right. Record minute or hour or day parameter, as outlined in #18 above.
20.	Local reaction at or near injection site: subcategories	Type of injection site reaction	If No.18 and 19 are completed, at least one of the following classifications must be checked. Multiple classifications can be checked. **Valid Values:** • Infected abscess • Sterile abscess • Cellulitis • Nodule • Reaction crosses joint • Lymphadenitis • Other, specify Additional information is required in the 'Comments' field if 'Other, specify' is selected. Examples of "other" local reactions that may be reported here include necrosis, papule, etc. See below (No.21). Also note the presence of any signs or symptoms (as under No 22.) associated with the reported reaction. If fever is presented, check No.63 'Fever' in Section 8.3 Other Defined Events of Interest. If treated with antibiotics (as appropriate by reaction type), indicate if resolution/improvement was temporally related to treatment.
21.	Comments (injection site reaction)	Description of 'Other' injection site reaction	Mandatory if 'Other, specify' is selected Once comment is added, it cannot be updated or deleted.

Local reaction at or near injection site			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
22.	**(Signs/symptoms):**	Possible signs/symptoms of an injection site reaction	Multiple items can be selected. **Valid Values:** • Swelling • Pain • Tenderness • Erythema • Warmth • Induration • Rash • Largest diameter of injection site reaction (cm): • Site(s) of reaction (Left arm: LA, Right arm: RA, Left leg: LL, Right leg: RL, Left gluteal: LG, Right gluteal: RG). If other sites, please specify. • Palpable fluctuance (Wavelike motion on palpation due to presence of liquid content) • Fluid collection shown by imaging technique (e.g. MRI, CT, ultrasound) • Spontaneous/surgical drainage Microbial results select “Microbial results” only if the result is positive. Record the laboratory result in the Comments field associated with this section (e.g., positive for S. aureus). • Lymphangitic streaking (Red streaks below the skin’s surface that follows the path of lymph draining from the site of infection via lymphatic vessels to regional lymph nodes) • Regional lymphadenopathy (Abnormal enlargement of the lymph nodes closest to the vaccination site)
23.	Comments	Additional description of the injection site reaction	Once comment is added, it cannot be updated or deleted.

8.2 Anaphylaxis or Other Allergic Events

The clinical signs and symptoms to be recorded in this section are closely aligned to the Brighton Criteria for anaphylaxis (see Anaphylaxis Worksheet under Surveillance Forms - AEFI for events managed as anaphylaxis). Refer to the Appendix of the anaphylaxis worksheet for definitions of the signs/ symptoms in this section. If the event is managed and reported as anaphylaxis, the completed anaphylaxis worksheet can be uploaded and attached to the client's AEFI record in Panorama.

For additional symptoms or signs not listed (e.g., sore throat, difficulty swallowing, difficulty breathing, chest tightness), record these in the 'Comments' field No. 34 corresponding with this section.



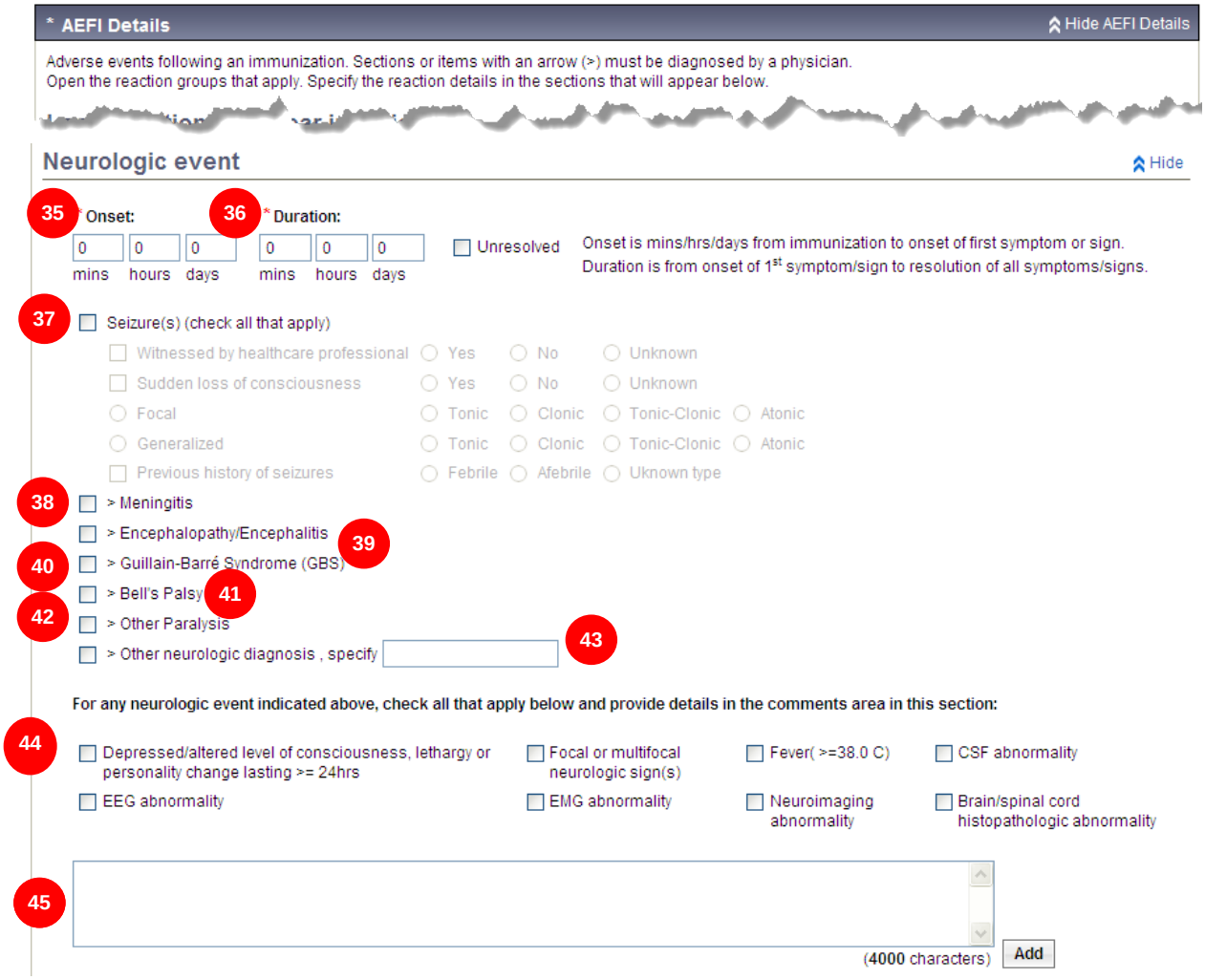
Anaphylaxis or Other Allergic Events - *See Anaphylaxis reporting form as reference (link on Page 20)			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
24	**(Type of allergic reaction):** • Anaphylaxis • Other allergic events	Classification of whether the allergic reaction was anaphylactic.	Mandatory field if event falls under this section. Select 'Clear' to untick. For a chosen event, describe the signs and symptoms by completing No. 25 to 34. Select 'Anaphylaxis' if the event was **managed** as anaphylaxis, regardless of how or whether it meets the Brighton Criteria. **If the event was Oculo-Respiratory Syndrome (ORS) , while this is considered an allergic-type reaction, do not report it as an 'Other allergic event'. Instead, report it in the SECTION: Other Defined Events of Interest.**
25.	Onset	Interval of time between the administrations of the vaccine(s) associated with the event and the onset of the first symptoms or signs related to the event.	Mandatory No.24 is selected. Record minute or hour or day parameter. It is not necessary to record more than one time parameter. Record minutes if event onset < 1 hour post-vaccination, hours if event onset < 24 hours post-vaccination, and days if event onset 1 or more days post-vaccination. If hours or days are recorded, record the number of **complete** hours or days between vaccine administration and onset of event.
26.	Duration	Interval of time from the onset of the first symptom until the symptom was resolved.	Mandatory if No.24 is selected and has resolved. Record minute or hour or day parameter, as outlined in #25 above. If unresolved, leave this blank and must check 'Unresolved' on the right.
27.	Skin/Mucosal > Generalized	Generalized skin/mucosal signs and symptoms of allergic reaction	If Skin/Mucosal is selected, user must select either Generalized or Localized. If Generalized is selected, user must select at least one of the following sub-level items. **Valid Values:** <u>Location</u> • At injection site • Non-injection site <u>Signs and symptoms</u> • Urticaria (hives/allergic rash) • Erythema • Pruritus • Prickle sensation A GENERALIZED reaction is defined as one that covers <u>two or more</u> body locations (e.g., both arms) and cannot only affect the injection site. User must select either "at injection site" **and** "non-injection site" or "non-injection site", but not only "at injection site". If the skin/ mucosal event occurred only at the injection site, it should be reported as LOCALIZED. If client has both GENERALIZED and LOCALIZED skin/mucosal symptoms, select GENERALIZED.

Anaphylaxis or Other Allergic Events - *See Anaphylaxis reporting form as reference (link on Page 20)			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
28.	Skin/Mucosal > Localized	Localized skin/mucosal signs and symptoms and location of allergic reaction	If Skin/Mucosal is selected, user must select either Generalized or Localized. If the skin/ mucosal event occurred only at the injection site, it should be reported as LOCALIZED. If client has both GENERALIZED and LOCALIZED skin/mucosal symptoms, select GENERALIZED. For LOCALIZED Skin/Mucosal signs and symptoms, user must select either “at injection site” or “non-injection site”, not both. If Localized is selected, user must select at least one of the following sub-level items. **Valid Values:** Location • At injection site • Non-injection site Signs and symptoms • Urticaria (hives/allergic rash) • Erythema • Pruritus • Prickle sensation Though not mandatory, user should select both location and at least one of the signs/symptoms.
29.	Skin/Mucosal > Eyes	Eye-related signs and symptoms of allergic reaction	If Skin/Mucosal is selected, user must select at least one of the sub-level items. Valid Values: • Red • Itchy If ‘Red’ is selected in Skin/Mucosal – Eyes, specify in the ‘Comments’ field whether it was unilateral or bilateral. If unilateral, specify which eye. If bilateral and event is classified as Oculo-Respiratory Syndrome, report the bilateral red eyes in 8.3 Other Defined Events of Interest and not in the allergy section.

Anaphylaxis or Other Allergic Events - *See Anaphylaxis reporting form as reference (link on Page 20)			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
30.	Skin/Mucosal > Angioedema	Affected areas of angioedema of allergic reaction.	Angioedema should not be reported unless this was a visible objective sign, i.e., provider-observed skin or mucosal swelling. If these are experienced as symptoms (subjective descriptions by the client such as "my tongue feels thick") but not observable as signs, do not report 'angioedema'. If Skin/Mucosal > Angioedema is selected, user must select at least one of the sub-level items. **Valid Values:** • Tongue • Throat • Uvula • Larynx • Lip • Eyelids • Limbs • Other, specify If Other is selected, must specify the affected area in the text box given.
31.	Cardio-vascular	Cardio-vascular signs and symptoms of allergic reaction	If Cardio-vascular is selected, user must select at least one of the sub-level items. Select one or more of the items **Valid Values:** • Measured hypotension • Decreased central pulse volume • Capillary refill time >3sec • Tachycardia • Decreased or loss of consciousness

Anaphylaxis or Other Allergic Events - *See Anaphylaxis reporting form as reference (link on Page 20)			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
32.	Respiratory	Respiratory signs and symptoms of allergic reaction	If Respiratory is selected, user must select at least one of the sub-level items. Select one or more of the items **Valid Values:** • Sneezing • Rhinorrhea • Hoarse voice • Sensation of throat closure • Stridor • Dry cough • Tachypnea • Wheezing • Indrawing/retractions • Grunting • Cyanosis
33.	Gastro intestinal	Gastro-intestinal signs and symptoms of allergic reaction	If Gastro intestinal is selected, user must select at least one of the sub-level items. Select one or more of the items **Valid Values:** • Diarrhea • Abdominal pain • Nausea • Vomiting If GI symptoms/ signs are isolated and not considered to be allergic in origin, report these events under Section 8.3 Other Defined Events of Interest, No. 64 'Other severe events not listed above' and provide comments in No. 65 'Comments'. Do not report in the Anaphylaxis/ Other allergic events section.
34.	Comments	Description or additional information of the allergic reaction.	Once comment is added, it cannot be updated or deleted. For additional symptoms or signs that are anaphylactic/ allergic in nature and are not listed in the categories on the screen in this section (e.g., sore throat, difficulty swallowing, difficulty breathing, chest tightness), record these in this 'Comments' field.

8.3 Neurologic Event

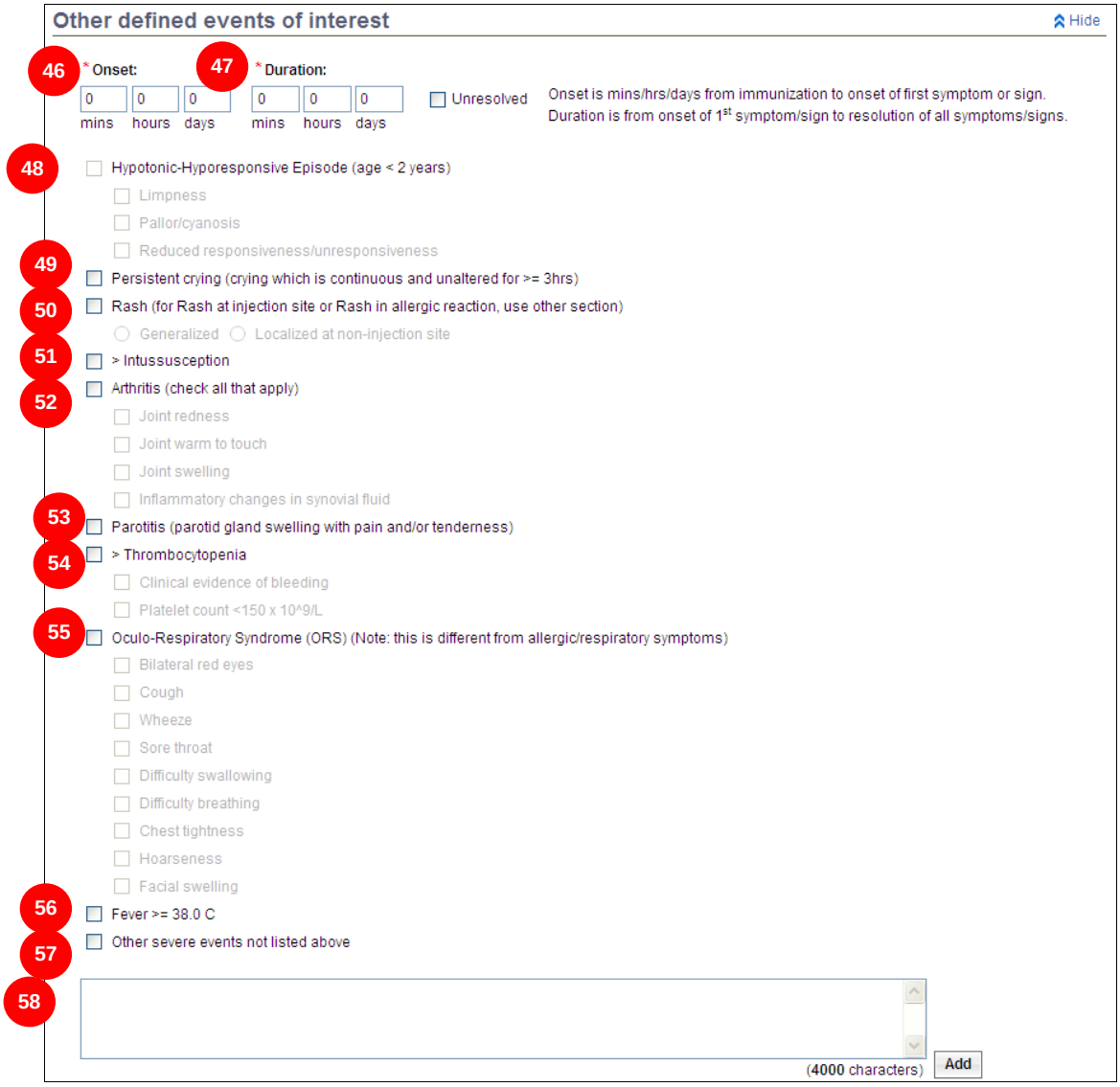


Neurologic Event			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
35.	Onset	Interval of time between the administrations of the vaccine(s) associated with the event and the onset of the first symptoms or signs related to the event.	Mandatory field if event falls under this section. Enter minutes, hours, OR days (only choose one). Record minute or hour or day parameter. It is not necessary to record more than one time parameter. Record minutes if event onset < 1 hour post-vaccination, hours if event onset < 24 hours post-vaccination, and days if event onset 1 or more days post-vaccination. If hours or days are recorded, record the number of **complete** hours or days between vaccine administration and onset of event. **Once this field is completed, one of No.37-43 must be checked.**

Neurologic Event			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
36.	Duration	Interval of time from the onset of the first symptom until the symptom was resolved.	Mandatory field if event falls under this section and has resolved. Record minute or hour or day parameter as outlined in item #35 above. If unresolved, leave this blank and must check 'Unresolved' on the right.
37.	Seizure	Whether the event is a seizure History, signs and symptoms of the seizure event	**If selected, must check and answer all of the following items:** • Witnessed by healthcare professional (Yes; No; Unknown) • Sudden loss of consciousness (Yes; No; Unknown) • Previous history of seizures (Febrile; Afebrile; Unknown type) If "Previous history of seizures" involved both febrile and afebrile, select 'Unknown type' and enter full history in 'Comments' because at this time, it is not possible to choose both and the system forces selection of one type. **Must answer one of these items:** • Focal (Tonic; Clonic; Tonic-Clonic; Atonic) • Generalized (Tonic; Clonic; Tonic-Clonic; Atonic) Categories of seizure reportable are only Focal or Generalized tonic, clonic, tonic-clonic and atonic. To report Myoclonic or Absence (formerly called Petit Mal) Seizure, select No. 43 "Other neurologic diagnosis" and specify.
38.	Meningitis	Whether the event is meningitis	Must be diagnosed by physician
39.	Encephalopathy/Encephalitis	Whether the event is encephalopathy/encephalitis	Must be diagnosed by physician
40.	Guillain-Barre Syndrome (GBS)	Whether the event is GBS	Must be diagnosed by physician
41.	Bell's Palsy	Whether the event is Bell's Palsy	Must be diagnosed by physician
42.	Other Paralysis	Whether the event involves other diagnosis of paralysis	Must be diagnosed by physician

Neurologic Event			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
43.	Other neurologic diagnosis, specify	Whether the event involves other neurologic diagnosis	Must be diagnosed by physician Must specify the diagnosis in the text box **Anaesthesia/Paresthesia is recorded in this field.**
44.	Select other findings	Select signs and diagnostic findings related to the neurologic event	For any neurologic event indicated above, check all that apply below and provide details in the comments area **Valid Values:** • Depressed/altered level of consciousness, lethargy or personality change lasting >=24hrs • Focal or multifocal neurologic sign(s) • Fever (>=38.0 C) If "Fever (>=38.0 C)" occurred in association with the neurologic event, report it here and **do not** select Fever (>=38.0 C) again under 8.2 'Other Defined Events of Interest'. • CSF abnormality • EEG abnormality • EMG abnormality • Neuroimaging abnormality • Brain/spinal cord histopathologic abnormality
45.	Comments	Description or additional information of the neurologic reaction.	Once comment is added, it cannot be updated or deleted.

8.4 Other Defined Events of Interest

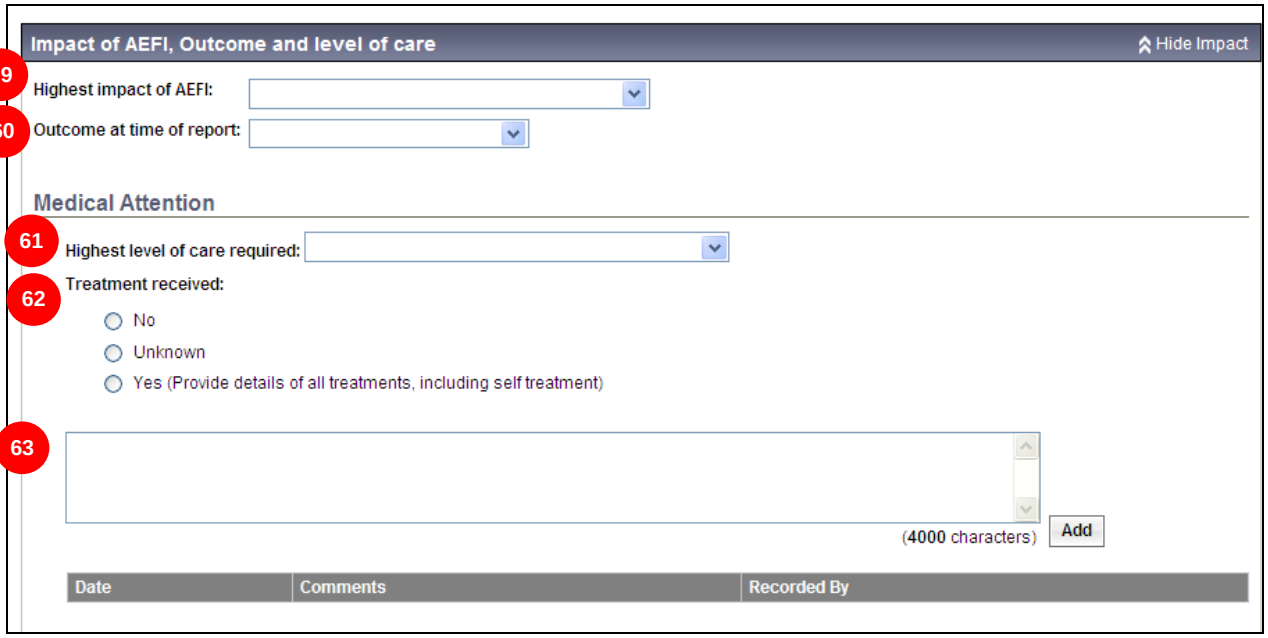


Other Defined Events of Interest			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
46.	Onset	Interval of time between the administrations of the vaccine(s) associated with the event and the onset of the first symptoms or signs related to the event.	Mandatory field if event falls under this section. Enter minutes, hours, OR days (only choose one). Record minute or hour or day parameter. It is not necessary to record more than one time parameter. Record minutes if event onset < 1 hour post-vaccination, hours if event onset < 24 hours post-vaccination, and days if event onset 1 or more days post-vaccination. If hours or days are recorded, record the number of **complete** hours or days between vaccine administration and onset of event. Once this field is completed, one of No.55-64 must be checked.
47.	Duration	Interval of time from the onset of the first symptom until the symptom was resolved.	Mandatory field if event falls under this section and has resolved. Record minute or hour or day parameter as outlined in item #46 above. If unresolved, leave this blank and must check 'Unresolved' on the right.
48.	Hypotonic-Hyporesponsive Episode (age <2 years)	Whether the event involved hypotonic-hyporesponsive episode in a patient <2 years of age	Once checked, at least one sub-item must be checked. Check all that apply. **Valid Values:** • Limpness • Pallor/cyanosis • Reduced responsiveness/unresponsiveness Do not use the HHE checkbox if the patient is two (2) years of age or older, instead please check "Other severe or unusual events not listed above" and describe the episode.
49.	Persistent crying (crying which is continuous and unaltered for >= 3hrs)	Whether the event involved persistent crying/screaming	

Other Defined Events of Interest			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
50.	Rash (not localized at injection site)	Whether the event was generalized rash or localized rash at non-injection site	Rash. Only report rash in this section if it is not at an injection site, and if it is non-allergic. Otherwise report the rash in the appropriate earlier section (Local Reaction at or near Injection Site, or Anaphylaxis or Other Allergic Events (Skin/ Mucosal: Urticaria). Once checked, at least one sub-item must be checked. Check all that applies. **Valid Values:** • Generalized • Localized at non-injection site. When possible provide a written description of the rash primary lesion(s) (bulla, cyst, macule, nodule, papule, plaque, pustule, vesicle, wheal), and/or secondary skin change(s) (scaling, atrophy, excoriation, fissure ulcer). If localized at non-injection site is selected, specify the location of the site in 'Comments'.
51.	Intussusception	Whether the event was intussusception	Must be diagnosed by physician
52.	Arthritis	Whether the event was arthritis	Once checked, at least one sub-item must be checked. Check all that applies. **Valid Values:** • Joint redness • Joint warm to touch • Joint swelling • Inflammatory changes in synovial fluid
53.	Parotitis (parotid gland swelling with pain and/or tenderness)	Whether the event was parotitis	Parotitis should only be reported after mumps-containing vaccine. Please refer to Section IX of Immunization Manual, page 18.
54.	Thrombocytopenia	Whether the event was thrombocytopenia	Must be diagnosed by physician. Once checked, at least one sub-item must be checked. Check all that applies. **Valid Values:** • Clinical evidence of bleeding • Platelet count <150 $X10^9$/L If clinical evidence of bleeding is checked and petechial rash is presented as a symptom, enter petechial rash in 'Comment'. When possible, indicate the lowest platelet count, and provide any additional pertinent information in comments, including the clinical evidence for spontaneous bleeding.

Other Defined Events of Interest			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
55.	Oculo-Respiratory Syndrome (ORS)	Whether the event was ORS	If client presents any of the symptoms below but is not suspected to have ORS, go to 8.1 and select other allergic reaction and enter information under 'Comment'. Once checked, at least one sub-item must be checked. Check all that apply. **Valid Values:** • Bilateral red eyes • Cough • Wheeze • Sore Throat • Difficulty swallowing • Difficulty breathing • Chest tightness • Hoarseness • Facial swelling
56.	Fever >= 38.0 C	Whether the event was high fever	Check only if it is not associated with a neurologic condition (see No. 46).
57.	Other severe events not listed above	Whether the severe/unusual event involved diagnosis not listed in all listed classifications above.	Other severe events not listed above: choose this category only if the event cannot be reported using a more appropriate existing category, as these data cannot be readily analyzed or alerted Once checked, description and possible classification of the event must be entered in Comments.
58.	Comments	Description or additional information of the 'Other defined event of interest'.	Once comment is added, it cannot be updated or deleted.

9.0 IMPACT OF AEFI, OUTCOME AND LEVEL OF CARE



Impact of AEFI, Outcome and Level of Care			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
59.	Highest impact of AEFI	Level of interference of AEFI to client's daily activities	Definitions of daily activities differ between adult (e.g. work, exercise, social commitment, etc) and child (eating, sleeping, playing, etc) **Valid Values:** • Did not interfere with daily activities • Interfere with but did not prevent daily activities • Prevented daily activities
60.	Outcome at time of report	Client's outcome at time of report	**Valid Values:** • Fatal • Fully recovered • Not yet recovered (if at least one of the reported AEFIs is unresolved) • Permanent Disability/Incapacity • Unknown If 'Fatal' is selected, enter date of death into the associated date of death field. Also enter date of death in client's demographics in Panorama.

Impact of AEFI, Outcome and Level of Care			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
61.	Highest level of care required	Highest level of care received by the client after AEFI	Hospitalization means admission to hospital. Assessment in an emergency room setting without formal admission to hospital should not be reported as hospitalization. If hospitalized, enter admission and discharge dates for analysis of length of stay, which is used as a seriousness criterion. **Valid Values:** • Admitted to Hospital **(must have been admitted, not seen on an outpatient basis or only visited ER)** • Emergency Visit • Non urgent visit to a health professional (seen by a health care professional e.g., at a physician's office or walk in clinic for the assessment and/or treatment of the reported AEFI. • None • Resulted in prolongation of existing hospitalization • Telephone advice from a health professional If Admitted to Hospital or Resulted in prolongation of existing hospitalization is selected, date fields on admission and discharge date will become visible for entry. If not visible, dates of care must be entered in 'Comments'. See below (No.70)
62.	Treatment received	Treatment received by client after AEFI, including self-treatment	**Valid Values:** • No • Unknown • Yes If Yes is checked, must describe treatment in 'Comments'. See below (No.70)
63.	Comments	Description and additional information about the medical attention given	Document details of all medical encounters with health professionals regarding the AEFI. Once comment is added, it cannot be updated or deleted.

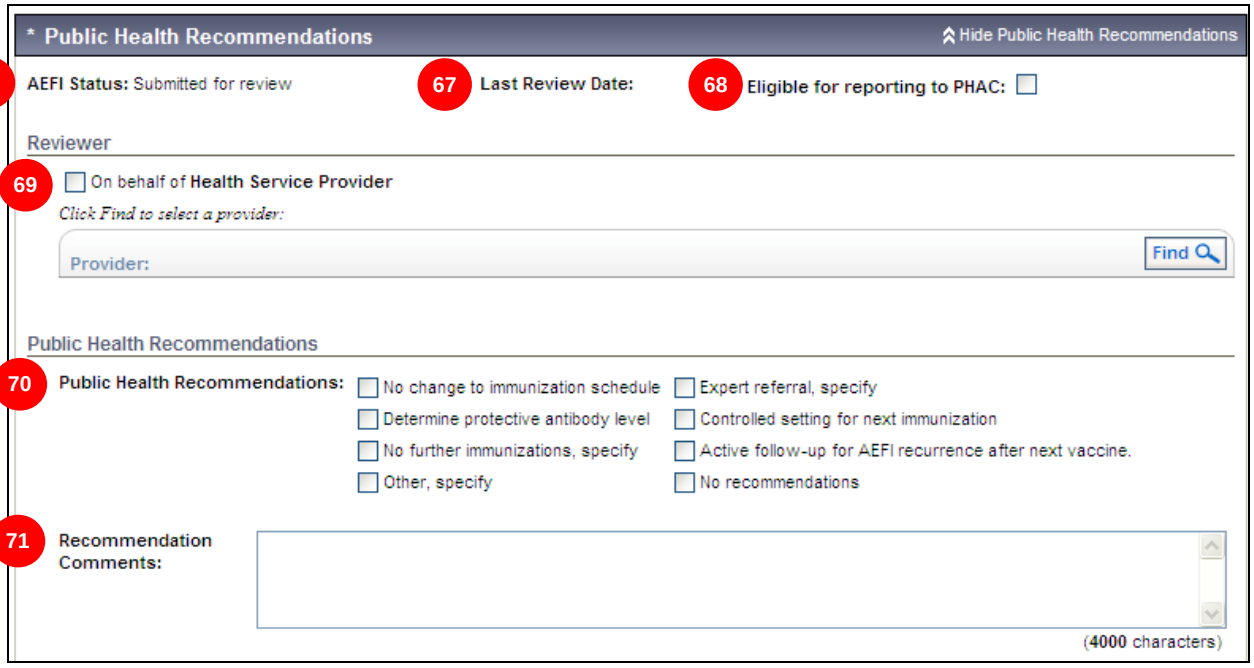
10.0 ASSIGNED TO

After completing this next section, click the “Save and Submit” button at the bottom of the screen in order to move to the next section 11.0 Public Health Recommendations. If the medical health officer requires a consultation from BCCDC Immunization Programs and Vaccine Preventable Diseases Service, email Dr. Monika Naus (monika.naus@bccdc.ca) and include the client ID and Adverse Event ID in your email; do not use the ‘assigned to’ function within Panorama for this purpose.

Assigned To			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
64.	Workgroups	Workgroup that reporter/reviewer wishes to assign the AEFI report to.	Must select a Workgroup in order to submit the form. Can only select ONE workgroup at a time. Instructions on selection are per regional health authority policy.
65.	Panorama Users	Specific Panorama users whom the reporter/reviewer wishes to assign the AEFI report to.	Once a workgroup is selected, the corresponding Panorama Users will be available for selection. Only one user can be assigned at a time. Can track the assignees through Work Management at the top of the page. If the first and last name of a user are known but unsure which workgroup he/she belongs to, user can use the ‘Look Up Users’ function and search by organization (i.e. health authorities), first and last name. If there are corresponding workgroups, they would appear for selection. For more advanced search, use Search instead of Type.

11.0 PUBLIC HEALTH RECOMMENDATIONS

This section displays upon saving and submitting the AEFI for review. Reporter and assignees can complete/edit this section via resubmission and review. After completing the review, if the client has contraindication to a vaccine or needs precautionary arrangement before the next immunization visit for a vaccine, reporter should enter the relevant information in "Special Considerations" (see Section 12.0).

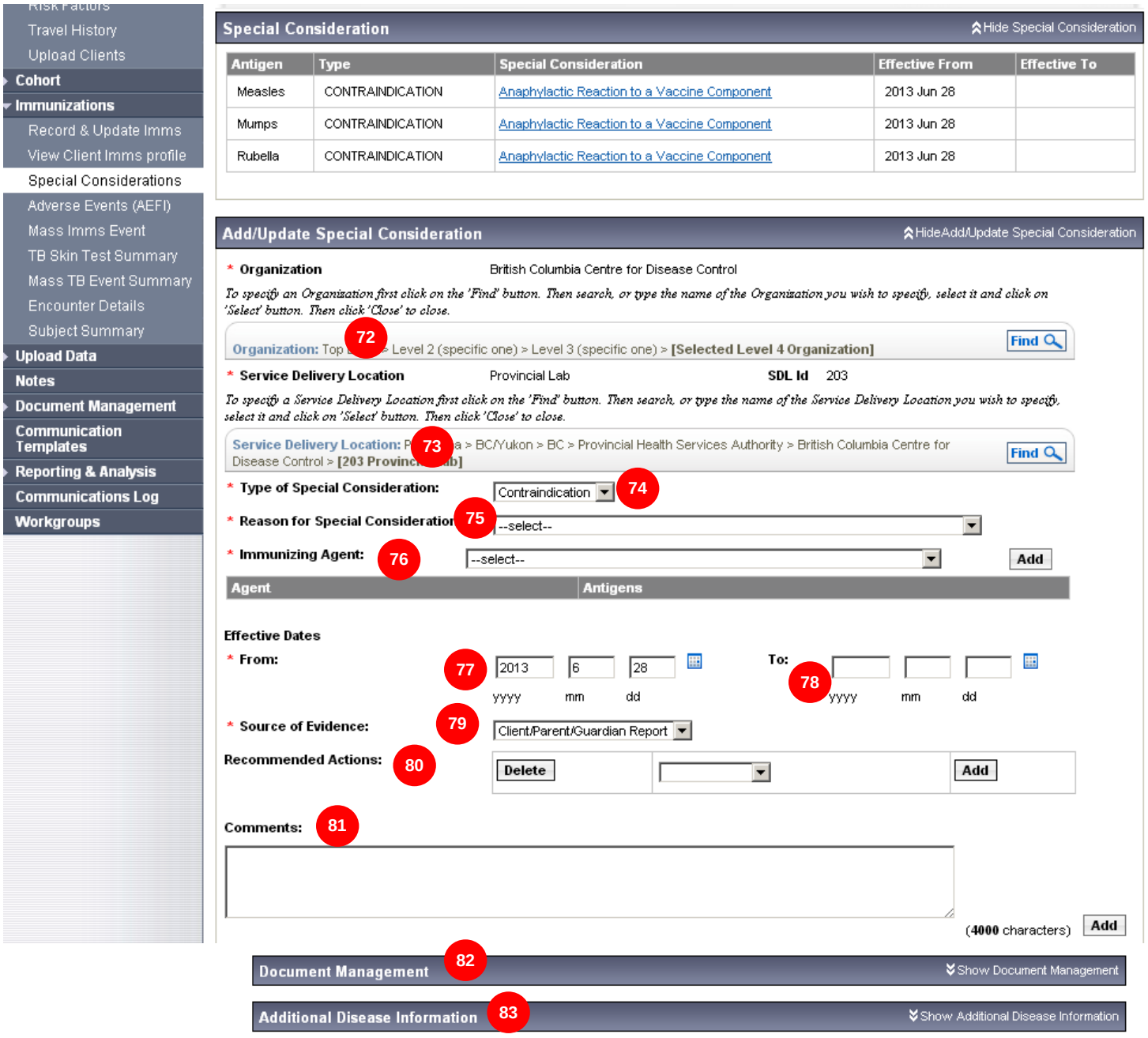


Public Health Recommendations			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
66.	AEFI Status	Status of the AEFI report	**System-generated Values:** • Draft (Saved as draft, not submitted) • Submitted for review (Submitted but review not complete) • Review complete
67.	Last Review Date	Non-functional field	User can ignore this field
68.	Eligible for reporting to PHAC	Whether the event is reportable to the Public Health Agency of Canada	Leave this field blank. BCCDC will be extracting all AEFI reports for reporting to PHAC, as has been historically done in iPHIS. In a future enhancement to Panorama, there will be changes to allow for specification of AEFI that are not reportable or have been reported among non-residents of BC, as is possible for communicable disease reports.

Public Health Recommendations			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
69.	On behalf of Health Service Provider	Name and Title of the user entering the recommendations	Check this field if the user is entering the recommendations on behalf of another provider. Select 'Find' and enter the name of the provider. For advanced search, use 'Search' instead of 'Type'.
70.	Public Health Recommendations	Reviewer's recommendation(s) for the reported AEFI	Must check at least one recommendation and click 'Add Recommendations". If that selection includes 'specify', then you must provide a comment or you will be prompted to do so before going to the next step. **Valid Values:** • No change to immunization schedule • Determine protective antibody level • **No further immunizations, specify (also enter information under "Special Considerations" as contraindication, see Section 12)** • Expert referral, specify • **Controlled setting for next immunization (also enter information under "Special Considerations" as precaution, see Section 12)** • Active follow-up for AEFI recurrence after next vaccine • **Other, specify (if the client has contraindication, exemption, or needs precaution for a vaccine, enter information under "Special Considerations", see Section 12)** • No recommendations
71.	Recommendation Comments	Explanation of the given recommendation	Explanation should include the rationale for this recommendation including any supplementary information on which it was based that may not be contained in the previously recorded fields. If 'determine protective antibody level' is chosen in #70, record the specific antibody determinations recommended unless only a single antigen vaccine was associated with the adverse event (e.g., hepatitis A) and this is obvious. Once a comment is added, it cannot be updated or deleted.

12.0 SPECIAL CONSIDERATIONS

This section is separate from the AEFI report. User can access this section on the left sidebar. Once a contraindication or exemption has been added for a client, the associated vaccine will be removed from the immunization forecaster. If the contraindication or exemption is subsequently removed, the associated vaccine will be reconsidered in the immunization forecaster. Select Save at the bottom of the page to submit the information. The submitted information will appear at the top of the section.



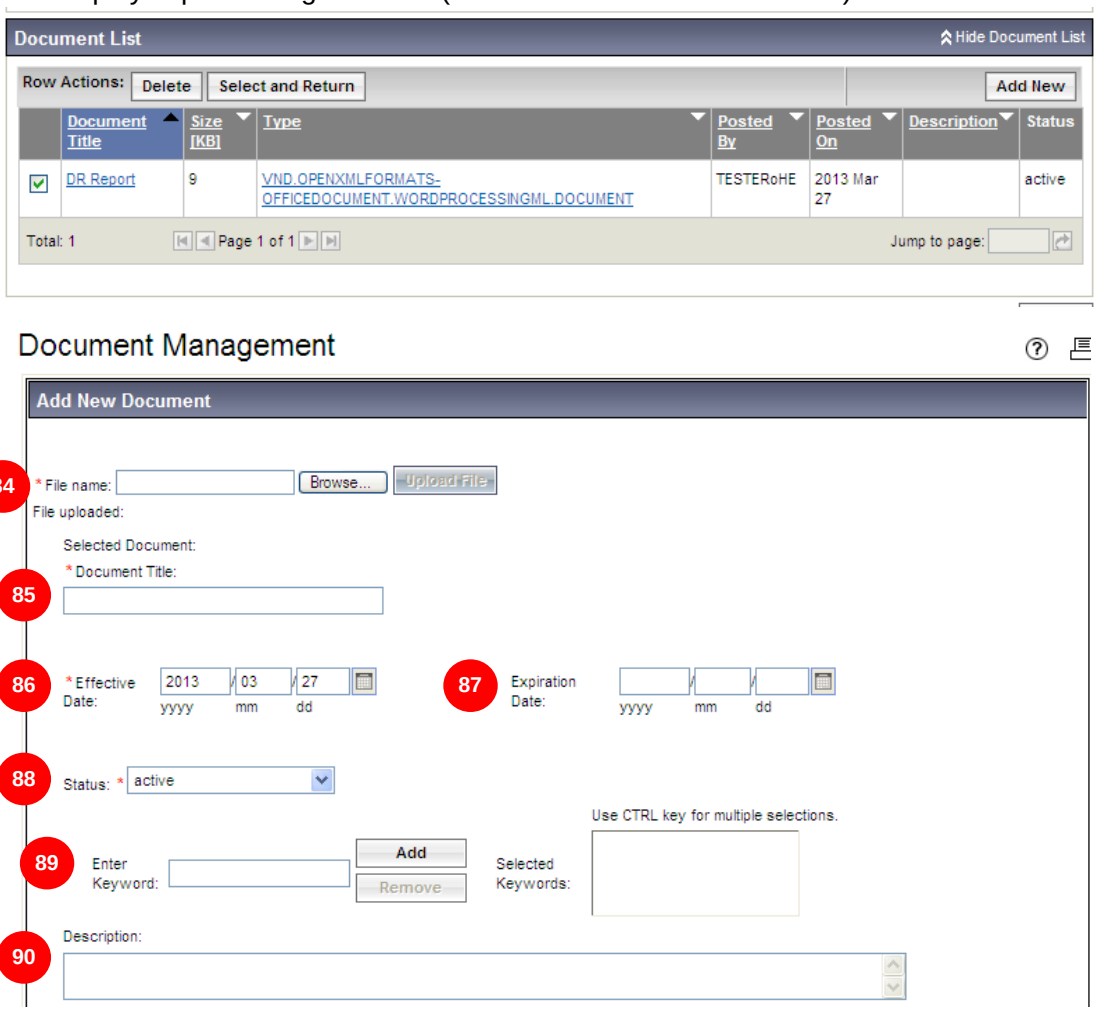
Special Considerations			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
72.	Organization	Branch office of the Panorama user logged-in	See No. 4 for instructions.
73.	Service Delivery Location	Branch office of the Panorama user logged-in	See No. 5 for instructions.
74.	Type of Special Consideration	Description of the special consideration of the client for immunization	**Must select one of the items before submitting the report for special consideration** **Valid Values:** • Contraindication (select if the client has a medically recommended contraindication including a public health recommendation for no further immunization of a vaccine) • Exemption (select if client does not need to be immunized because of prior disease or immunity, or a religious/ philosophical objection to vaccination) • Precaution (select if there is a specific precaution to be taken for future immunization e.g., next immunization in series to be given in an emergency room setting).

Special Considerations			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
75.	Reason for Special Consideration	Reasons for the different special consideration selected in No.74	**Valid Values:** **Contraindication** • Anaphylactic reaction to a previous dose of the vaccine or any of its antigens • Anaphylactic reaction to a vaccine component • Anaphylactic reaction to latex • Family history of congenital immunodeficiency • Guillain-Barre syndrome • History of intussusception • Other (Specify in comments) • Pregnancy • Severely immunocompromised (for live vaccines) • Uncorrected congenital gastrointestinal conditions **Exemption** • Allergy testing required • Antibodies/antitoxin levels required • Client/Parent/Guardian refusal: religious/philosophical • Client refusal • Consultation with BCCDC recommended • Immunity – lab evidence • Immunity – previous disease • Immunity – previously immunized • Immunization not given on recommendation of physician • Medical – clinical decision • Other severe or unusual events (specify in comments) • Parental/guardian refusal • Recent administration of blood product – containing antibodies • Referred to doctor **Precaution** • Blood coagulation disorder • Chronic underlying illness • Fever ≥ 40.5 C within 48 Hrs of administration of prior dose • History of febrile convulsion • History of vasovagal syncope • Immunized in emergency health care setting • Immunize in presence of parent

Special Considerations			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
			• Immunosuppression (for inactive vaccines) • Major local reaction to previous dose • Monitor longer after immunization • Needle phobia • Other (specify in comments) • Recent administration of blood product –containing antibodies • Recent administration of live virus vaccine • Renal Hep B formulation required
76.	Immunizing agent	Vaccine associated with the special consideration in No.74 and 75	Must select one vaccine or immunizing agent in the list. Must select Add after selection. If the agent contains more than one component, user can select which component(s) is/are associated with the special consideration.
77.	Effective Dates - From	Start date of the special consideration	Must be entered to submit the special consideration. This field is defaulted to the date of entry, but this date can be changed.
78.	Effective Dates - To	End date of the special consideration	This field is defaulted to blank. Enter an 'effective to date' if there is a known end date for the contraindication, exemption or precaution, such as the recommended length of time for deferral of active vaccination following immunoglobulin receipt.
79.	Source of evidence	Source of evidence for special consideration	Must select one item to submit the special consideration. If available, user should attach the relevant document under Document Management (See No.82 below). **Valid Values:** • Client/Parent/Guardian report • Health Care Provider • Lab Report • Legal Document • MHO • Medical records transfer • Observed
80.	Recommended Actions		User can ignore this field
81.	Comments	Description and additional information about the special consideration	Once comment is added, it cannot be updated or deleted.
82.	Document Management		This field is non-functional currently. In the future when this field becomes functional, user should attach relevant documents here for the submitted special consideration.
83.	Additional Disease Information		This field is non-functional currently. User can ignore this field.

13.0 DOCUMENT MANAGEMENT

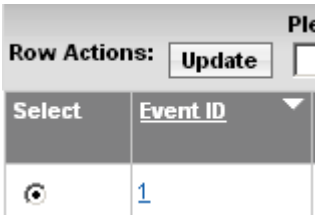
Note: This section displays upon saving the AEFI (either as draft or for submission).



Document Management			
No.	**Field name**	**Field definition**	**Instructions/ Further Information**
84.	File name	Searchable field for the document to be uploaded.	Only upload documents of pdf and jpeg file types.
85.	Document Title	Name of uploaded document	Naming Convention: <Document Name> <Document Type> Example: DR Report, ER Report
86.	Effective Date	Date the document was uploaded	
87.	Expiration Date	Non-functional field	User can ignore this field
88.	Status	Accept default value of 'Active'.	
89.	Keywords	Non-functional field	User can ignore this field
90.	Description	Non-functional field	User can ignore this field

14.0 UPDATING INFORMATION

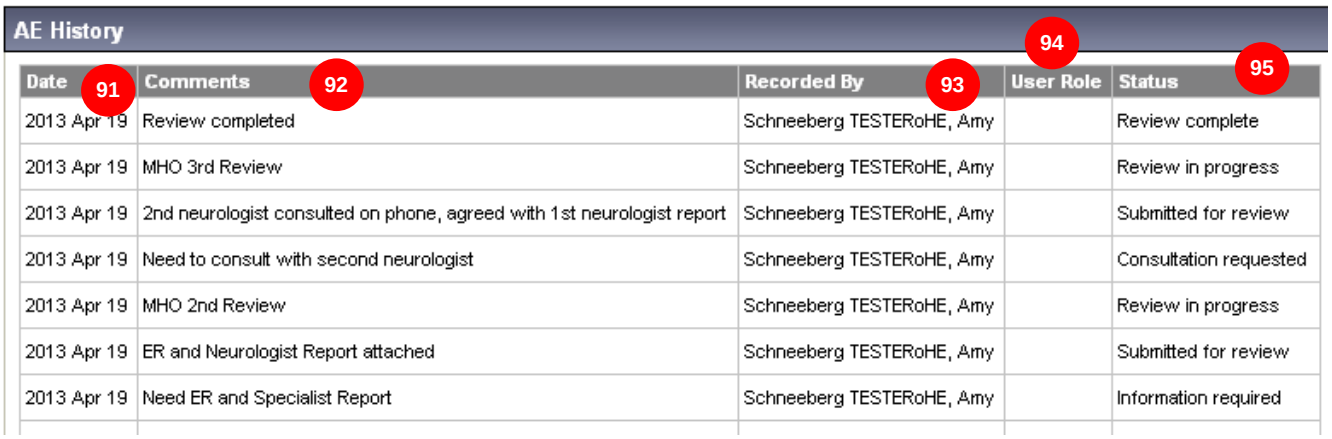
Once an AEFI report has been submitted, user can update the AEFI report (attach documents such as ER reports, change submitted information, submit additional information). To update, select the AEFI report and select 'Update' in Adverse Event Summary.



This will bring the user to the AEFI report with all the fields editable. Comments and recommendations submitted previously will NOT be editable. All changes made in the update need to be recorded in the appropriate comment box of the edited section. Once the edits are done, select the assignee, and select 'Save and Resubmit'. A comment box will pop up and user will be prompted to enter comments. User should record all the edits that have been made in this comment box. This process can be done repeatedly.

15.0 AE HISTORY

AE History illustrates the chronological progress of the AEFI report from beginning to most recent status.



AE History

Date (91)	Comments (92)	Recorded By (93)	User Role (94)	Status (95)
2013 Apr 19	Review completed	Schneeberg TESTERoHE, Amy		Review complete
2013 Apr 19	MHO 3rd Review	Schneeberg TESTERoHE, Amy		Review in progress
2013 Apr 19	2nd neurologist consulted on phone, agreed with 1st neurologist report	Schneeberg TESTERoHE, Amy		Submitted for review
2013 Apr 19	Need to consult with second neurologist	Schneeberg TESTERoHE, Amy		Consultation requested
2013 Apr 19	MHO 2nd Review	Schneeberg TESTERoHE, Amy		Review in progress
2013 Apr 19	ER and Neurologist Report attached	Schneeberg TESTERoHE, Amy		Submitted for review
2013 Apr 19	Need ER and Specialist Report	Schneeberg TESTERoHE, Amy		Information required

AE History

No.	Field name	Field definition	Instructions/ Further Information
91.	Date	When the status was changed	
92.	Comments	Description of the status	User will be prompted to enter comments when the follow actions are taken at the top or bottom of the page. Comment should reflect the corresponding action. • Save and Resubmit (What has been updated and why) • Start Review (Who is reviewing and what phase of review) • Need more information (What information is needed and from who) • Need consultation (Who needs to be consulted and for what issue) • Review Complete
93.	Recorded By	Name of the user who made the change	
94.	User Role	Non-functional field	
95.	Status	Status of the report	All changes to the status are recorded. • Draft (Saved as draft but not submitted) • Submitted for review (Submitted or resubmitted) • Review in progress (Started review but has not completed review, resubmitted, or requested for more info) • Information required (Reviewed and requested for more info) • Consultation requested (Reviewed and requested for further consultation) • Review complete (Reviewed and gave recommendation, report completed)

16.0 REVIEW PROCESS (Optional)

The following steps are optional because users can choose to communicate and share updates through emails.

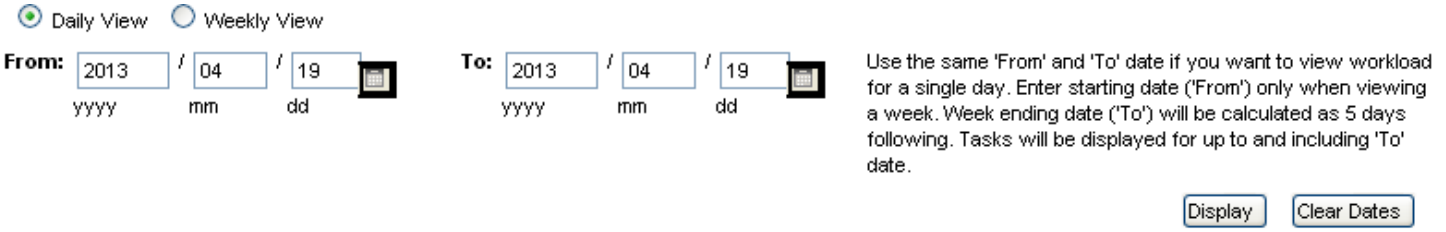
16.1 Start Review

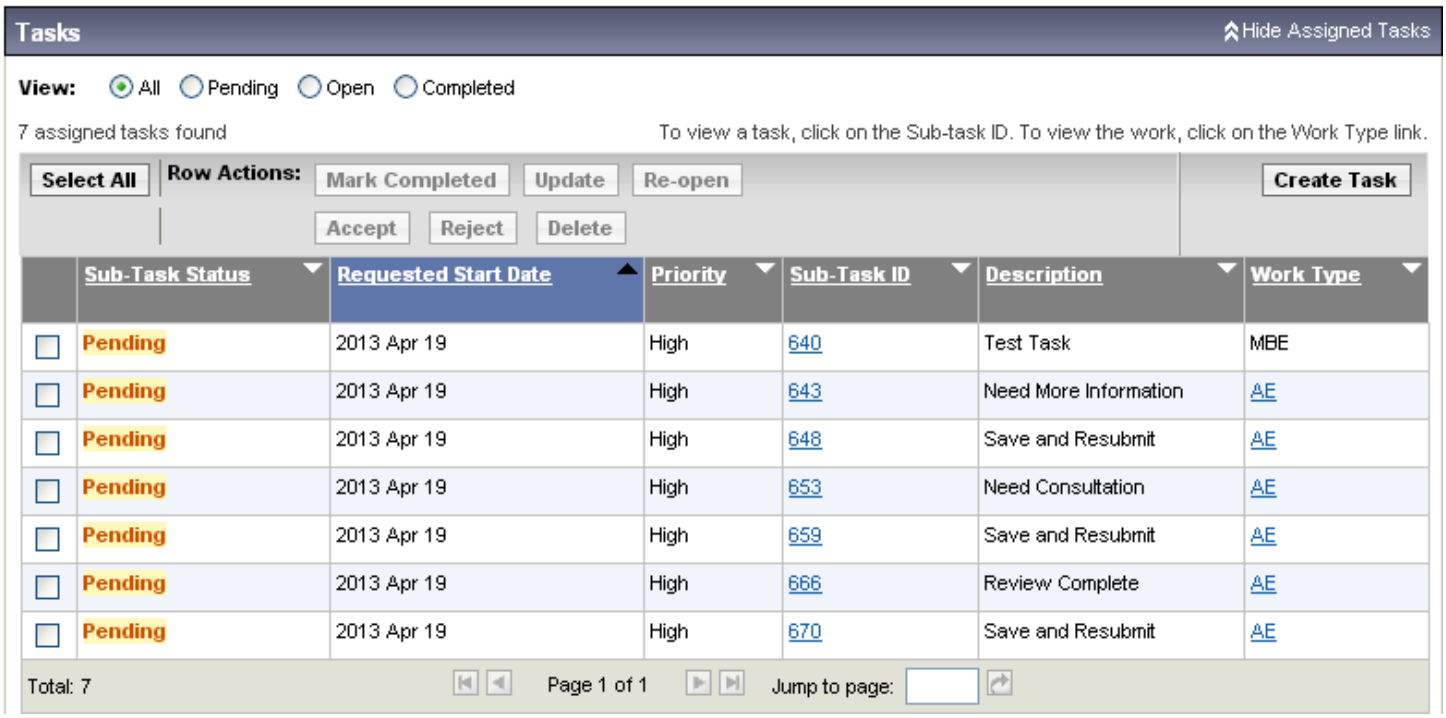
Once a report has been created, 'Warnings' with hazard sign will appear at the top of the client's page. User can check for a preview of the AEFI alerts of a client by clicking on the sign.

After the initial report submission, the reporter and assignees can choose the following options to proceed:

- Reporter to resubmit the report with updates (need to re-enter who to assign the report to)
- Assignees to start review (need to enter comment)

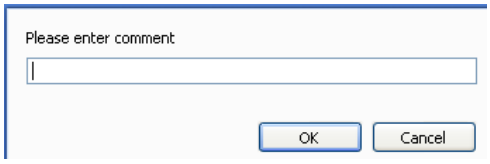
Only assignees will be alerted to review an AEFI report. The assignee(s) will be alerted in the Work Management page. Each new update will be labelled as 'Pending' item.





User needs to select 'Sub-Task ID' and then accept or reject the submission. If accepted, the Sub-Task Status will change to 'Open'. If rejected, the task will disappear. Select AE under 'Work Type' to be redirected to the associated AEFI report. User can filter the assigned tasks by range of dates and sub-task status. The 'Description' highlights the status of the AEFI report. All assigned tasks for all AEFI reports at the different stages of the review will be recorded here even after they have been completed.

Once user is redirected to the client's AEFI report, select 'Start Review'. User will be prompted to enter a comment. Please enter 'Who is reviewing' and 'What phase of review'.



The page will then refresh to begin the review. The assignee will now have the following new options, all requiring a comment before submission and assigning to another user (i.e. back to the reporter):

- Need more information (comment on 'What information is needed', 'Why it is needed', and 'From who')
- Need consultation (comment on 'Who needs to be consulted' and 'For what issue')
- Review complete (comments on 'Recommendations')

16.2 Review Complete

The final reviewer will receive the request to review in the Work Management page. Access the AEFI report and complete section 11.0 Public Health Recommendation (see 11.0 for instructions). Select 'Review Complete' if no further information and review are needed.