Reviewing, Coding, and Assessing Adverse Event Reports from the Public in PV-Works
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Source Document: CVB-SOP-0038, Receipt of Adverse Event Reports Submitted to the Center for Veterinary Biologics from the Public

This document describes the procedures for reviewing, coding, and assessing Adverse Event Reports (AERs) received from the public in the PV-Works database application.

Adverse Event Reports (also called cases) from the public are entered and verified within PV-Works as per CVB-WI-0123, Entering and Verifying Adverse Event Reports from the public in PV Works.

To find the list of cases ready for review, select the query “Cases to Review” on the left panel of the main screen. Only verified cases will appear when the “Cases to Review” query is run.
From the list of cases to review, select a case to highlight it and then open it by double clicking on it, or selecting the red check mark next to the case number above as shown below:
The case will open in the Complaints screen (the default screen) as shown below:
Ensure the case has been verified and there is a checkmark present, as noted below in the
‘Complaint types’ section.
Review the information on the screen as a summary of the case.

Go to the Products screen to ensure that a biological product is selected as a “suspect product” as
shown below:
More than one product may have been administered and will be listed at the bottom of the
screen. Determine the “suspect product(s).”
Note: Typically, all products are listed as suspect, but at least one must be selected in order to
assign ‘case serious’ and ‘causality’ in the Assessment screen.
VeDDRA Coding a Case:

To VeDDRA code a case, select the Event Narrative screen from the left menu as shown here:

The Event Narrative Screen will appear as follows:
Select the View/Edit Coding icon as shown:

The VedDRA Coding screen will appear as this:

Search the narrative text for all clinical signs and use the search function to find the respective VedDRA Low-level term for each sign.

In the narrative, the clinical signs reported are lethargy, vomiting (dry heaves) and labored breathing (dyspnea). So, in this example, enter lethargy in the search text field and search by selecting the search button as shown here:
Pet started having labored breathing, dry heaving, and was lethargic for 2 days after IN bord. By the time owner alerted us on 6/5/20, her respiratory subsided, but she was still lethargic. Owner has not called back, so presumably dog has made a full recovery at this point.
Select the respective Low-level term in the search result field as shown below:

After you select the proper Low-level term, save the code by selecting the Save button. An audit trail field will be displayed after saving the first VeDDRA code as shown below. From the pull-down menu, select “New Information Available” and then save. Proceed to the next clinical sign in the narrative until all are coded.
When the list of codes are complete for the case, save the VeDDRA coding screen:

If the following message appears, select NO:

If the following message appears, select YES:
Assessing a case

Select the Assessment link on the left-hand side of the screen as follows:
Provide an ABON assessment to the case utilizing the drop-down menu for the USDA Assessment AND Company Assessment field, as shown below:

Note: USDA Assessment does not query in the grid, but Company Assessment does, so provide the same ABON assessment for both.

It is not necessary to assign causality for the VeDDRA terms.
Indicate if the case is Serious with a checkmark in one of the (Y/N) boxes below ‘Serious?’, and assign ‘Reportability’ as Periodic or Immediate (3-Day Alert) in the drop-down menu as shown below:
Select the CVB Review screen link on the left side of the screen. Using the pull-down menu of the Final Actions/Review outcome field, select Reviewed as complete and select No More Information Expected toggle.
Complete the CVB review by returning to the Complaints screen and mark the case as Reviewed by selecting the checkmark as shown below:

Note: If the “Reviewed” option above the “Verification complete” is not visible, click the magnifying glass sign (circled below) and it will appear.
To close the case, select Save and exit, as shown below:

Select Save when the pop-out window appears, as shown below: