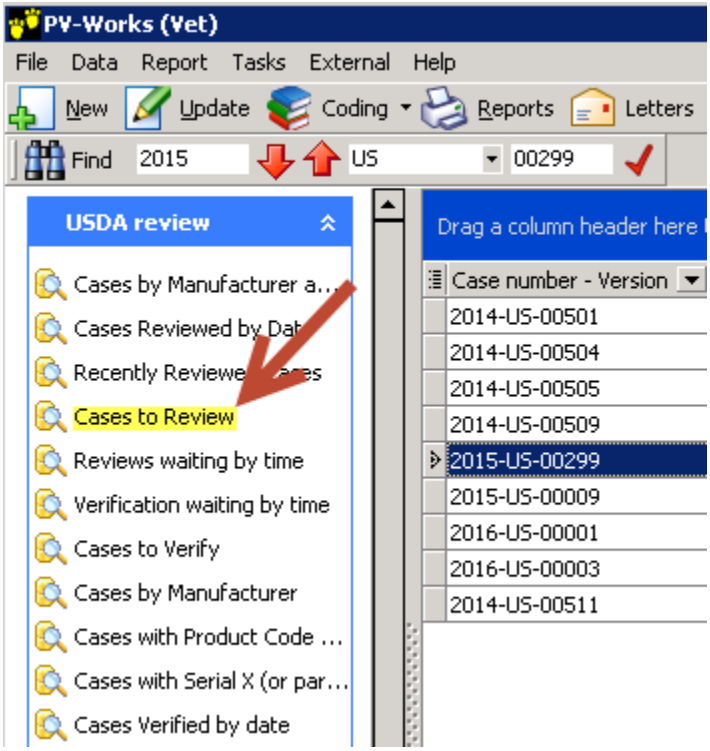
Reviewing, Coding and Assessing Adverse Event Reports in PV-Works

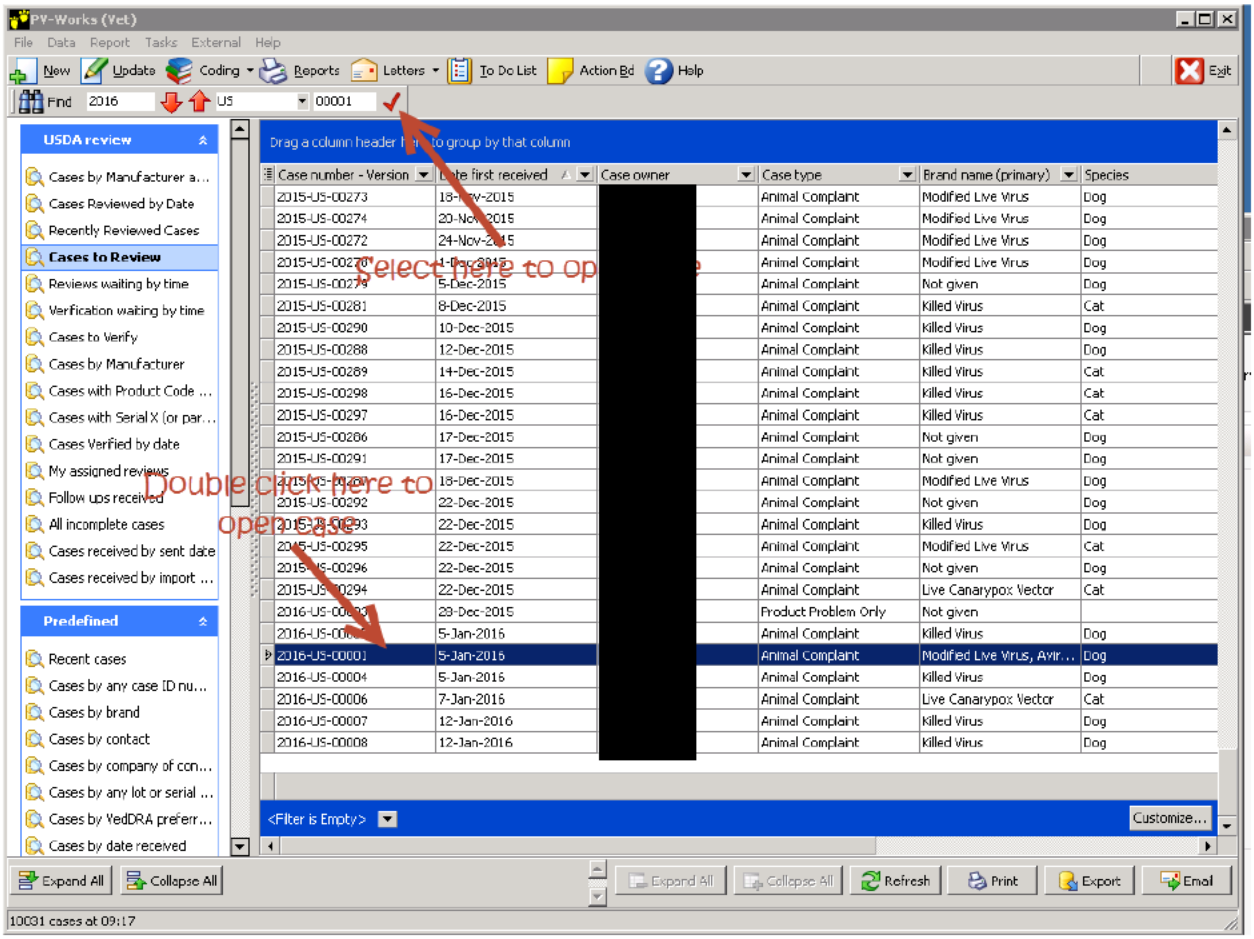
This document describes the procedures for reviewing, coding, and assessing Adverse Event Reports (AERs) in PV-Works database application.

Adverse Event Reports (also called cases) are entered and verified within PV-Works as per **ICWI0117**, *Entering and Verifying Adverse Event Reports in PvWorks*.

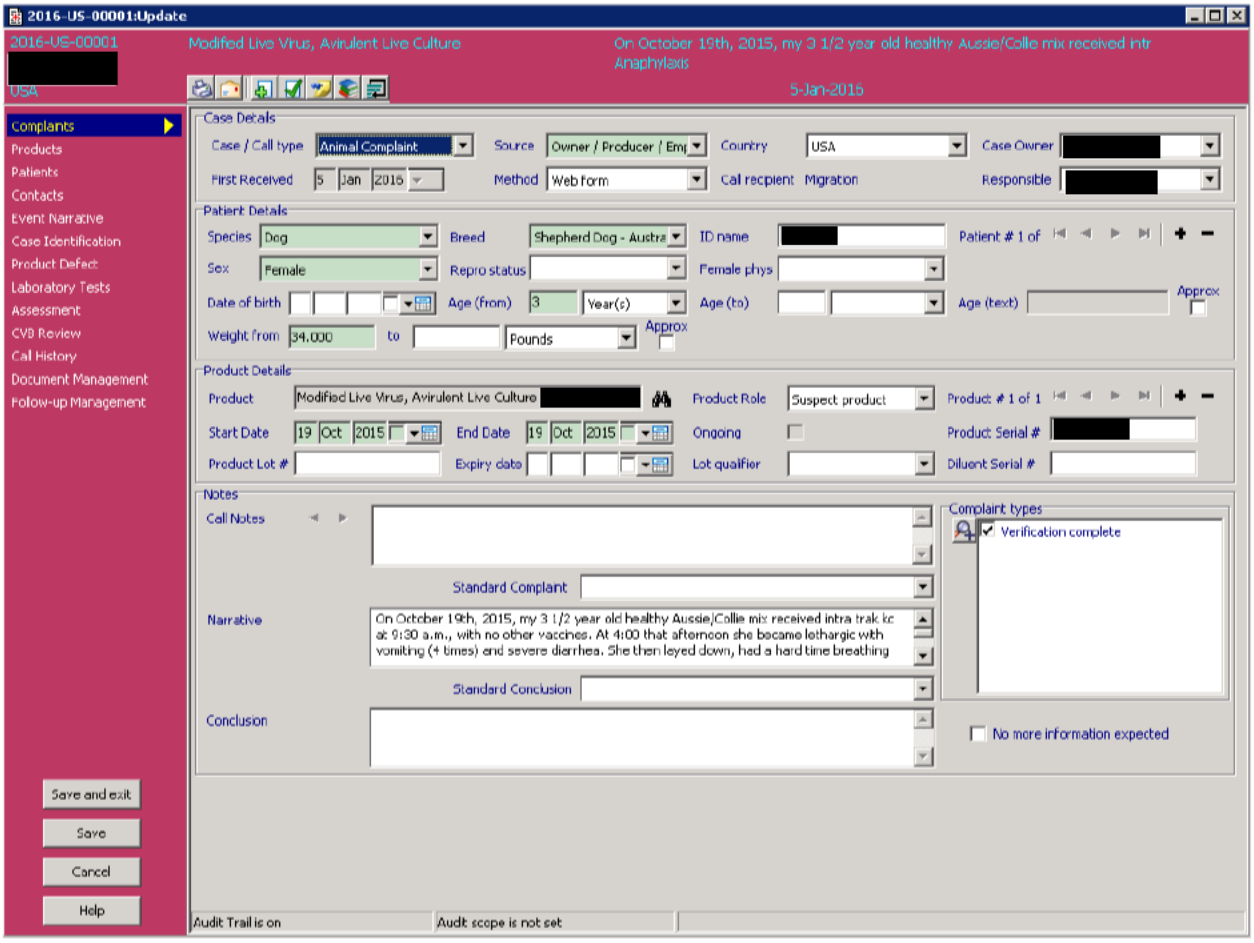
To find the list of cases ready for review, select the query "Cases to Review" on the left panel of the main screen.



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:



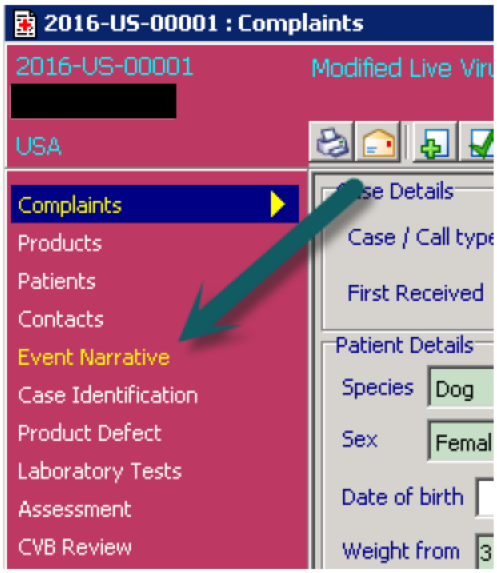
The case will open in the complaints screen (the default screen) as shown below:



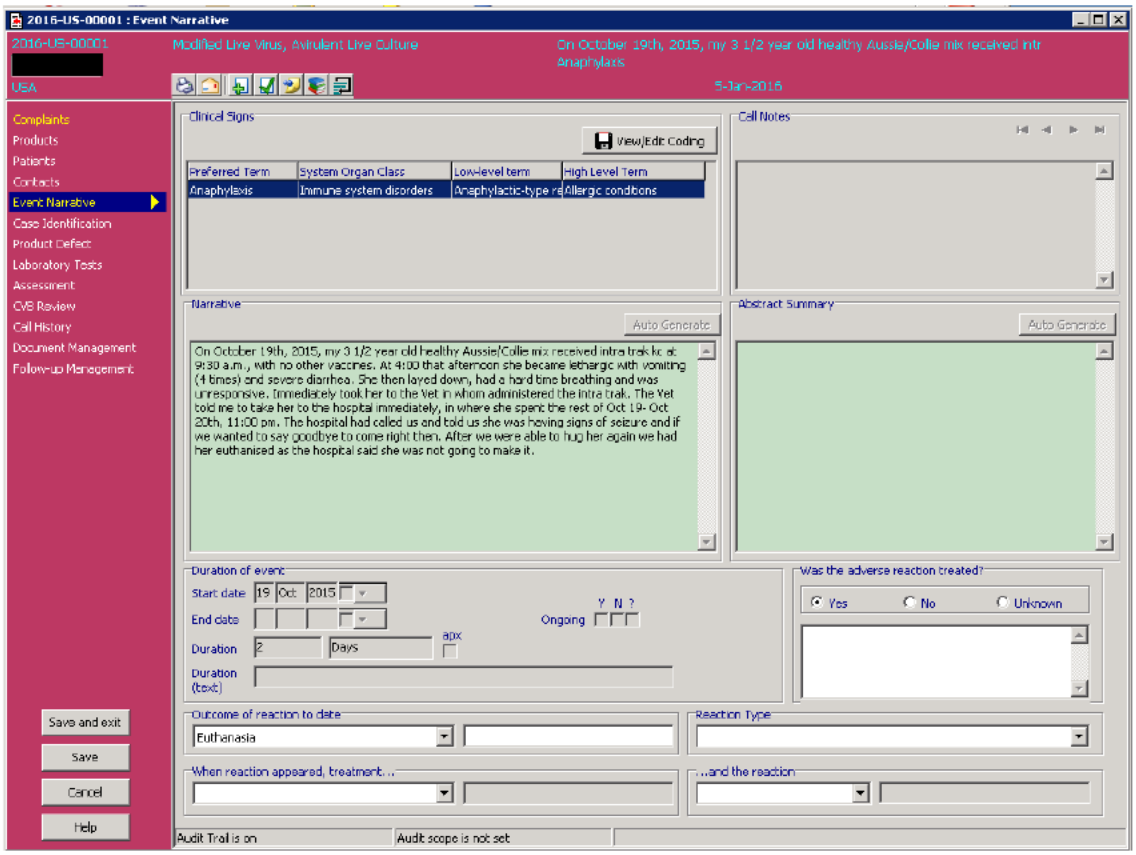
Review the information in this field as a summary of the case.

Coding a Case:

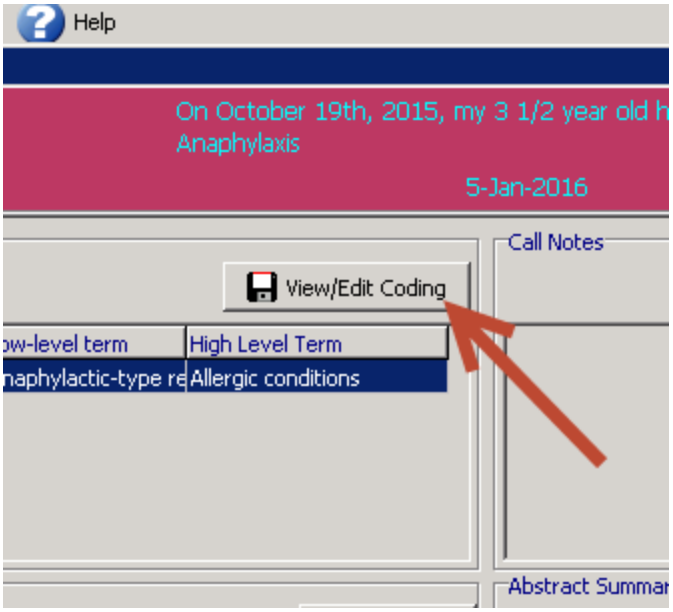
To code a case, select the Event Narrative screen from the left menu of the Complaint Screen as shown here:



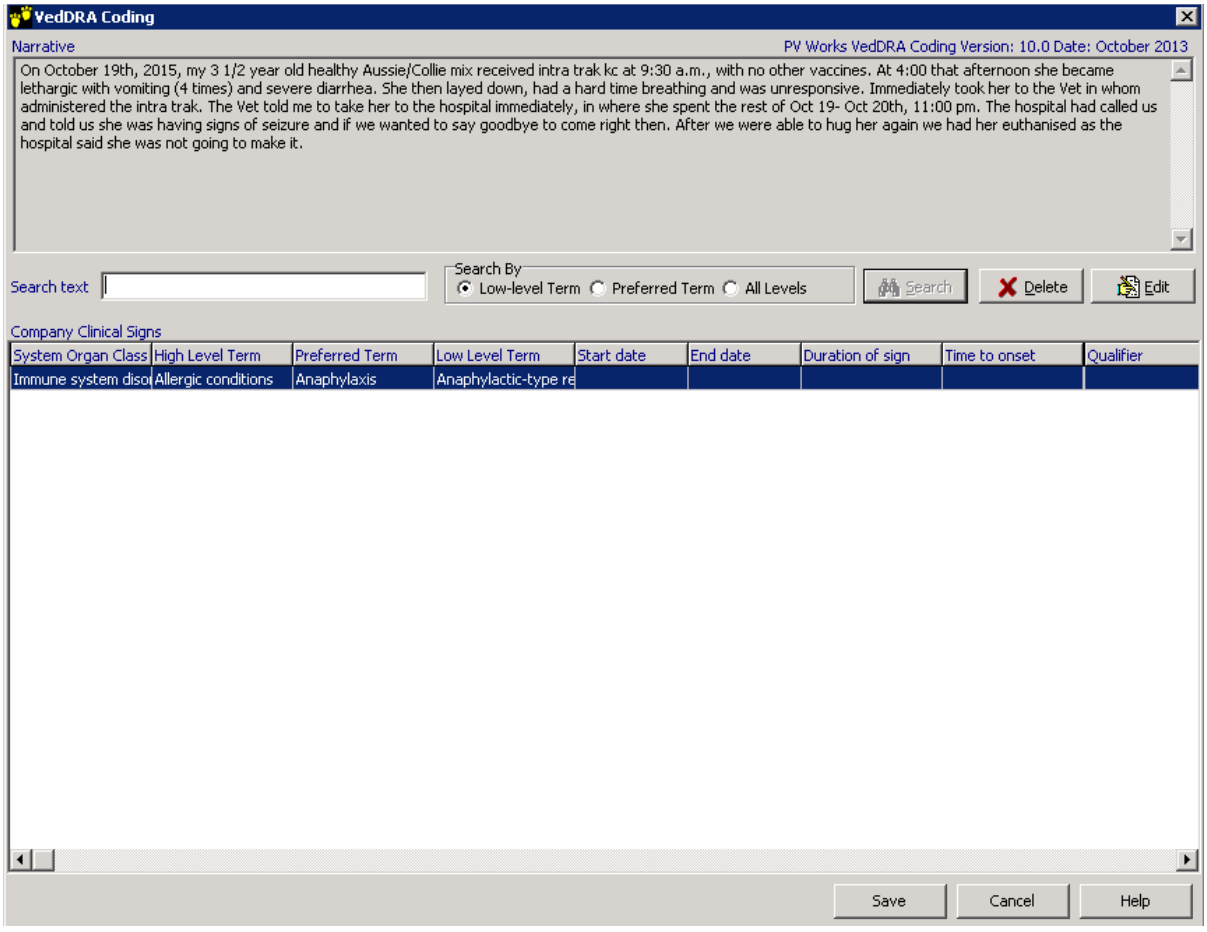
The Event Narrative Screen will appear as follows:



Select the View/Edit Coding icon as shown:



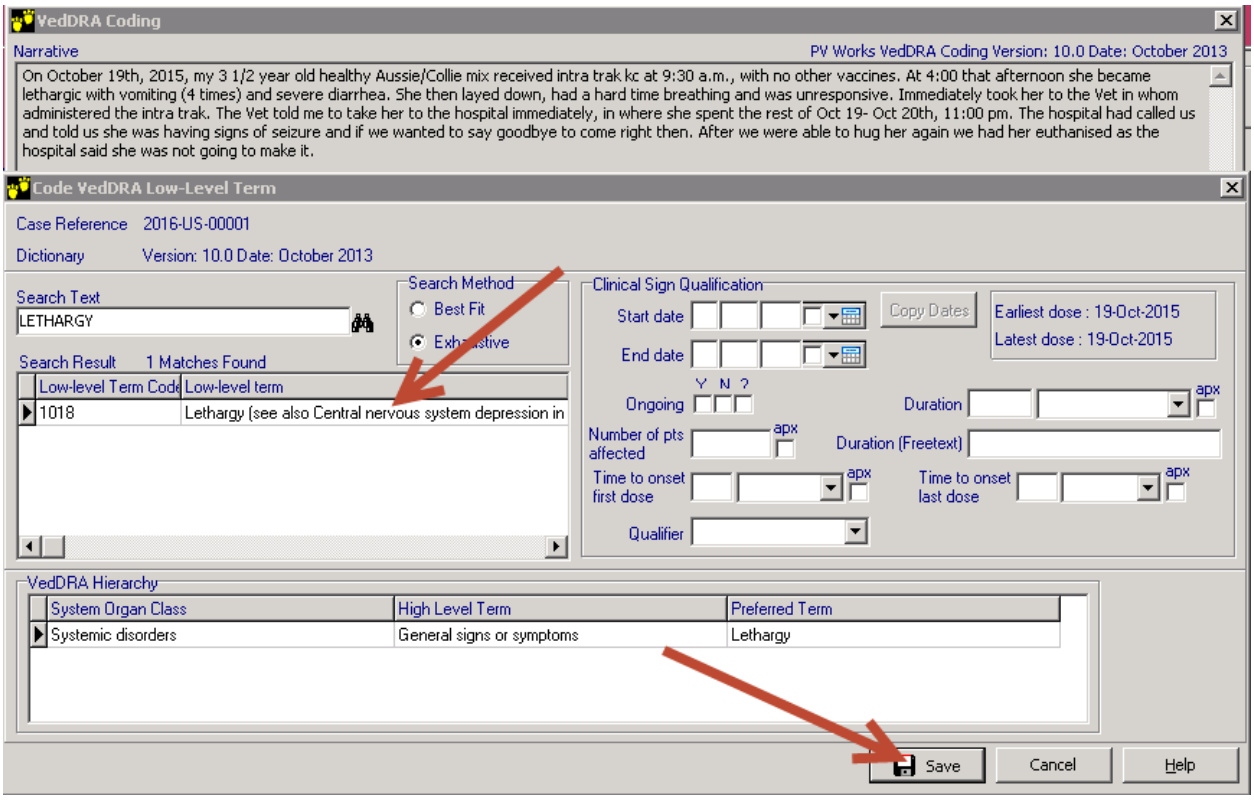
The VedDRA Coding screen will appear as this:



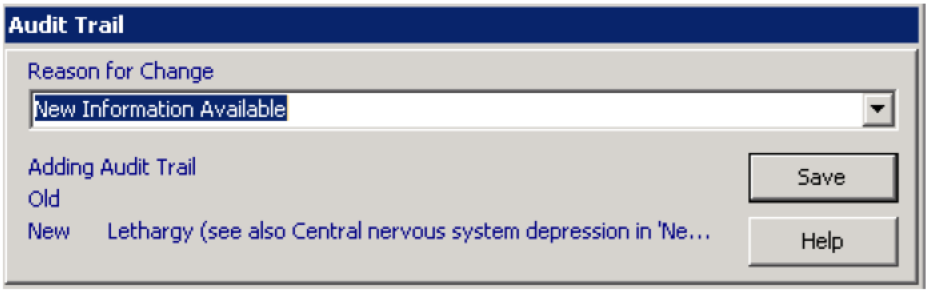
Search the narrative text for all clinical signs and use the search function to find the respective VedDRA Low-level term for each sign.

In the above narrative (page 5), the first clinical sign is lethargic, followed by vomiting and severe diarrhea. So, in this example, enter lethargy in the search text field and search by selecting the binocular icon as shown here:

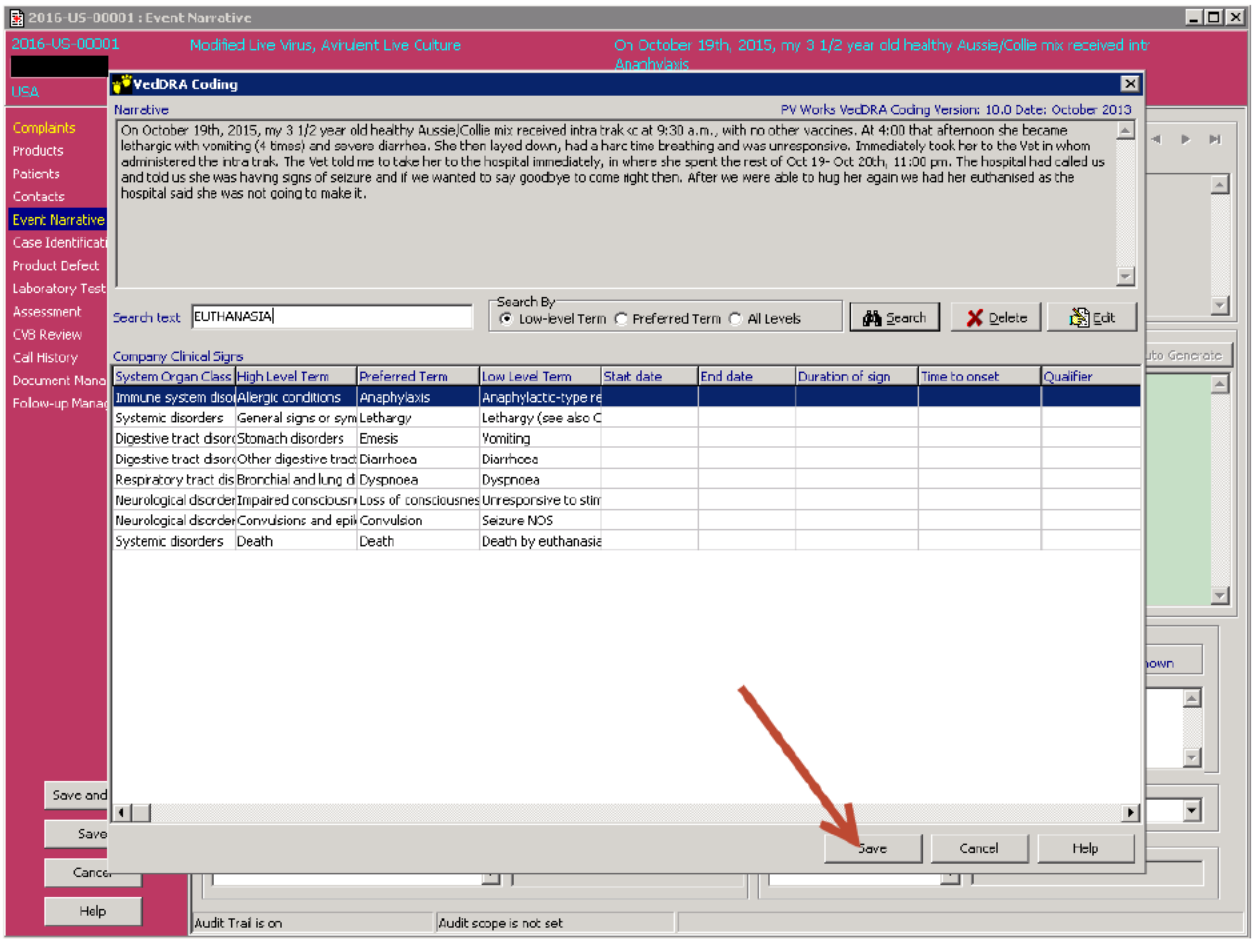
Select the respective Low-level term in the search result field as shown below:



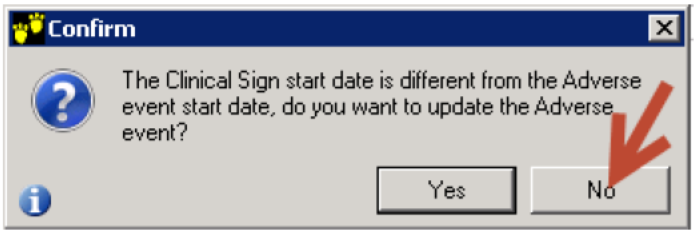
After you select the proper Low-level term, save the code by selecting the Save icon.
An audit trail field will be displayed after saving the first VedDRA code as shown below. From the pull-down menu, select "New Information Available" and then save. Proceed to the next clinical sign in the narrative until all are coded.



When the list of codes are complete for the case, save the VedDRA coding screen:

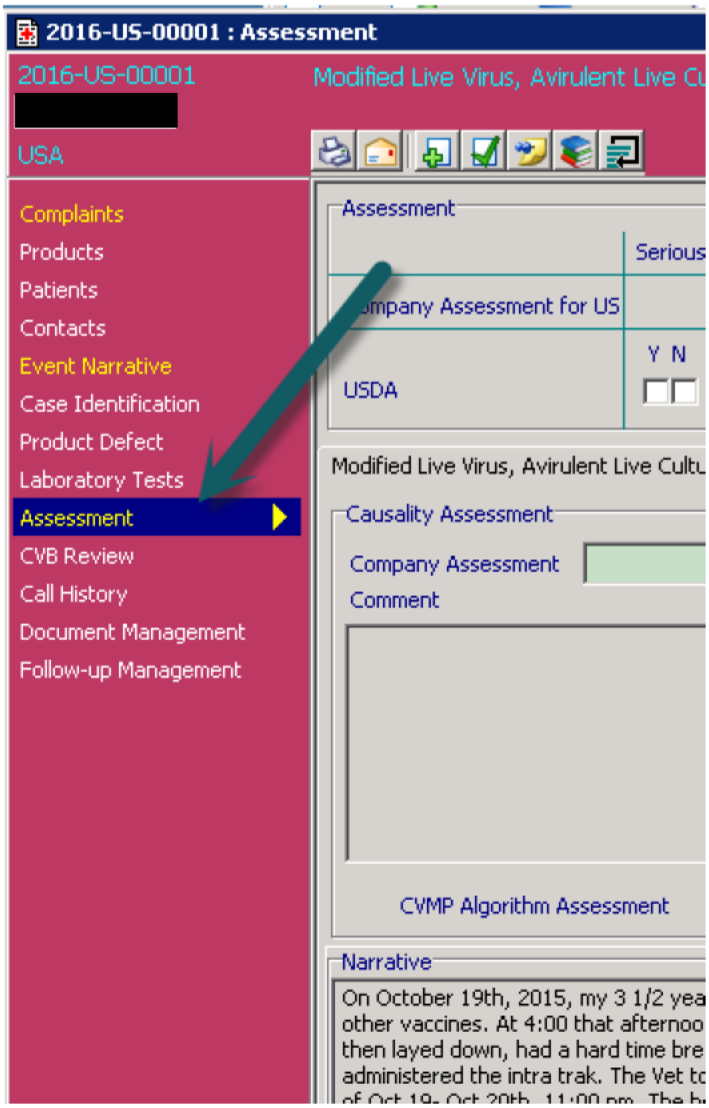


If the following message appears, select no:

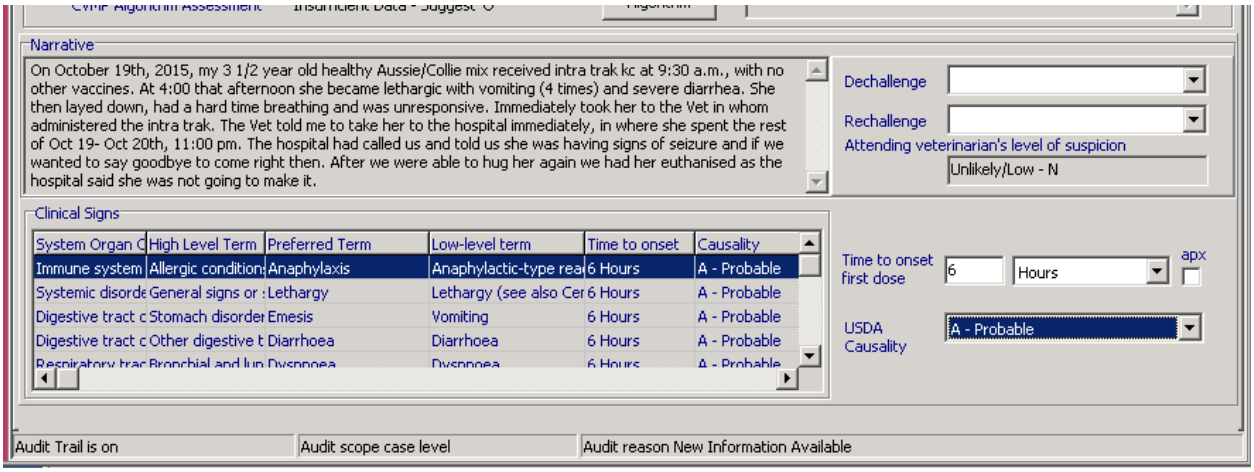


Assessing a case

Select the Assessment link on the left hand side of the screen as follows:



Assign the time to onset and the USDA causality assessment to each clinical sign for each product as shown below:



Complete the CVB review by selecting the CVB Review 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. Select Save and exit.