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Service

Veterinary Services

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## Reviewing, Coding, and Assessing Adverse Event Reports from the Public in PV-Works

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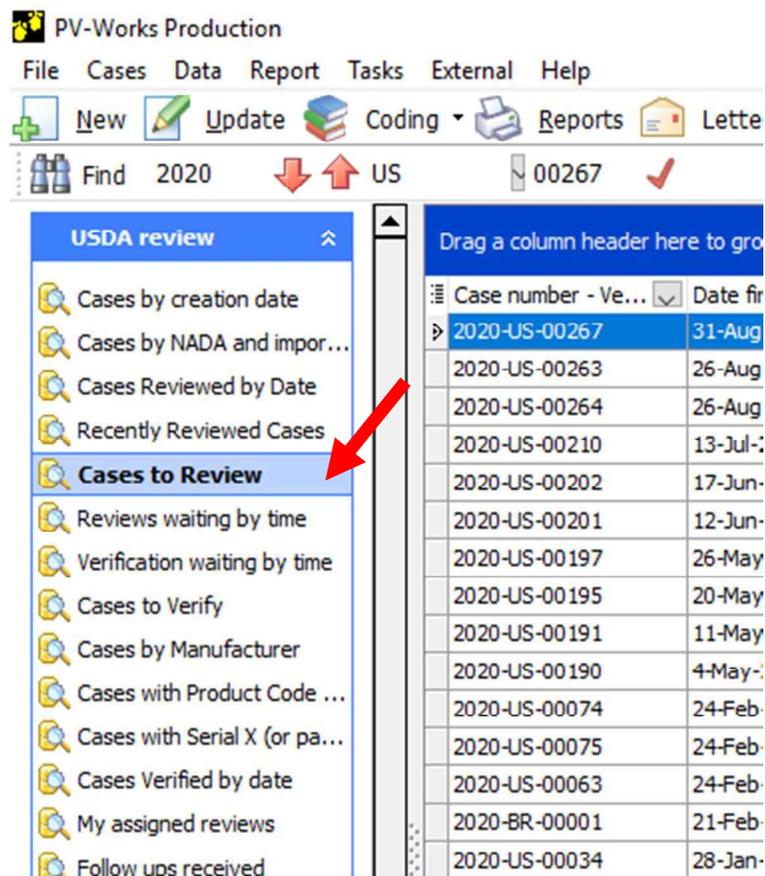
## Reviewing, Coding, and Assessing Adverse Event Reports from the Public in PV-Works

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.



The screenshot shows the PV-Works Production application interface. The top menu bar includes File, Cases, Data, Report, Tasks, External, and Help. Below the menu is a toolbar with icons for New, Update, Coding, Reports, and Letters. The status bar shows 'Find 2020' with up and down arrows, 'US', and '00267' with a checkmark. The left sidebar contains a list of queries under the 'USDA review' section. The 'Cases to Review' query is highlighted with a red arrow. The main window displays a table of cases with columns for Case number and Date first received.

Case number - Ve...	Date fir
2020-US-00267	31-Aug
2020-US-00263	26-Aug
2020-US-00264	26-Aug
2020-US-00210	13-Jul-
2020-US-00202	17-Jun-
2020-US-00201	12-Jun-
2020-US-00197	26-May
2020-US-00195	20-May
2020-US-00191	11-May
2020-US-00190	4-May-
2020-US-00074	24-Feb-
2020-US-00075	24-Feb-
2020-US-00063	24-Feb-
2020-BR-00001	21-Feb-
2020-US-00034	28-Jan-

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 screenshot shows the PV-Works Production application window. The menu bar includes File, Cases, Data, Report, Tasks, External, and Help. The toolbar contains icons for New, Update, Coding, Reports, Letters, To Do List, Action, and Help. The status bar shows 'Find 2020', 'US', and '00019' with a red checkmark. The left sidebar has a tree view with 'Cases to Review' selected. The main area displays a table of cases with columns: Case number - Ve..., Date first..., Case owner, Case type, Brand name (primary), Spe..., C..., and Product probl... The table contains 20 rows of case data. A red checkmark is next to the case number '2020-US-00019'. A red box highlights the case number '2020-US-00019' with the text 'Click here to open highlighted case'. Another red box highlights the case number '2020-US-00019' with the text 'Double click here to open case'. The status bar at the bottom shows '11447 cases at 07:59'.

Case number - Ve...	Date first...	Case owner	Case type	Brand name (primary)	Spe...	C...	Product probl...
2020-US-00267					Dog	Unit...	Adverse reactor
2020-US-00263					Dog	Unit...	Adverse reactor
2020-US-00264					Dog	Unit...	Adverse reactor
2020-US-00210	13-Jul-2020	Rick Dewald	Animal Complaint	Live Canarypox Vector	Cat	Unit...	Adverse reactor
2020-US-00202	17-Jun-2020	Rick Dewald	Animal Complaint	Killed Virus	Dog	Unit...	Adverse reactor
2020-US-00201	12-Jun-2020	Rick Dewald	Animal Complaint	Not given	Dog	Unit...	Adverse reactor
2020-US-00197	26-May-2020	Rick Dewald	Animal Complaint	Live Canarypox Vector	Cat	Unit...	Adverse reactor
2020-US-00195	20-May-2020	Rick Dewald	Animal Complaint	Modified Live Virus	Cat	Unit...	Adverse reactor
2020-US-00191	11-May-2020	Rick Dewald	Animal Complaint	Modified Live Virus	Dog	Unit...	Adverse reactor
2020-US-00190	4-May-2020	Rick Dewald	Animal Complaint	Not given	Dog	Unit...	Adverse reactor
2020-US-00074	24-Feb-2020	Rick Dewald	Animal Complaint	Not given	Dog	Unit...	Adverse reactor
2020-US-00075	24-Feb-2020	Rick Dewald	Animal Complaint	Not given	Dog	Unit...	Adverse reactor
2020-US-00063	24-Feb-2020	Rick Dewald	Animal Complaint	Modified Live Virus	Dog	Unit...	Adverse reactor
2020-BR-00001	21-Feb-2020	Rick Dewald	Animal Complaint	Killed Virus	Dog	Brazil	Adverse reactor
2020-US-00034	28-Jan-2020	Rick Dewald	Animal Complaint	Modified Live Virus	Dog	Unit...	Product problem
2020-US-00029	23-Jan-2020	Rick Dewald	Animal Complaint	Modified Live Virus and Avirulent Live Cul...	Dog	Unit...	Adverse reactor
2020-US-00022	15-Jan-2020	Rick Dewald	Animal Complaint	Not given	Dog	Unit...	Adverse reactor
2020-US-00017	15-Jan-2020	Rick Dewald	Animal Complaint	Killed Virus	Dog	Unit...	Adverse reactor
2020-US-00018	15-Jan-2020	Rick Dewald	Animal Complaint	Killed Virus	Dog	Unit...	Adverse reactor
2020-US-00021	15-Jan-2020	Rick Dewald	Animal Complaint	Killed Virus	Dog	Unit...	Adverse reactor
2020-US-00019	15-Jan-2020	Rick Dewald	Animal Complaint	Modified Live Virus	Dog	Unit...	Adverse reactor
2020-US-00020	15-Jan-2020	Rick Dewald	Animal Complaint	Modified Live Virus	Dog	Unit...	Adverse reactor
2020-US-00015	14-Jan-2020	Rick Dewald	Animal Complaint	Killed Virus	Dog	Unit...	Adverse reactor
2020-US-00016	12-Jan-2020	Rick Dewald	Animal Complaint	Modified Live Virus and Avirulent Live Cul...	Dog	Unit...	Adverse reactor
2020-US-00011	8-Jan-2020	Rick Dewald	Animal Complaint	Killed Virus	Dog	Unit...	Adverse reactor
2020-US-00010	8-Jan-2020	Rick Dewald	Animal Complaint	Not given	Dog	Unit...	Adverse reactor

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.

2021-US-03658:Update Production

2021-US-03658 Modified Live Virus We vac. 23 cats on 3/10/21. Cats started dyeing 2 days later We are into 12 days  
Rick Dewald  
United States 22-Mar-2021

**Complaints**  
Products  
Patients  
Contacts  
Event Narrative  
Case Identification  
Product Defect  
Laboratory Tests  
Assessment  
CVB Review  
Call History  
Document Management  
Follow-up Management

**Case Details**  
Case / Call type: Animal Complaint Information type: Confirmed AE report Source: NOS Other  
First received: 22 Mar 2021 Case owner: Rick Dewald Country: United States  
Date case first valid: 22 Mar 2021 Responsible: Rick Dewald Method: PVX (Public)  
Date latest follow up: Call recipient: Migration

**Patient Details**  
Species: Cat Breed: American Shorthair ID name: Cookie Patient #: 1 of 1  
Sex: Female Repro status: Neutered Female phys:  
Date of birth: Age (from): 1 Year(s) Age (to): Age (text):  
Weight from: 6.200 to: Pounds Approx

**Product Details**  
Product: Modified Live Virus 16D1.20 190 - Zoetis Inc. Product Role: Suspect product Product #: 1 of 1  
Start Date: 10 Mar 2021 End Date: 10 Mar 2021 Ongoing: Product Serial #: 467390C  
Product Lot #: Expiry date: 3 May 2022 Lot qualifier: Diluent Serial #:

**Notes**  
Call Notes:  
Standard Complaint:  
Narrative: We vac. 23 cats on 3/10/21. Cats started dyeing 2 days later We are into 12 days and still lost a cat today. we have lost 10 cats.. Cats healthy and Happy till vac. Vomiting and Listless and constant drooling, till death.  
Standard Conclusion:  
Conclusion:  
No more information expected

**Complaint types**  
 Verification complete

Save and exit  
Save  
Cancel  
Help

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.

2021-US-03319 Not on Rick Dewald United States 17-Mar-2021 Patient came in for Leptospirosis 1 year (SC RF) and Influenza 3wk (SC LF). Rece

**Complaints** Products Patients Contacts Event Narrative Case Identification Product Defect Laboratory Tests Assessment CVB Review Call History Document Management Follow-up Management

Product Definition  
 Dictionary Product  other combination products Product Role **Suspect product** Product Problem Type  Adverse reaction

Product Line 190 - Zoetis Inc. Generic Name Canine Influenza Vaccine, H3N2 & H1N1

Brand Name Killed Virus (Zoetis VANGUARD CIV)

Formulation Strength

Brand Description Killed Virus 15Q5.20 190 - Zoetis Inc. Product Unsubstantiated  Satisfaction Guarantee

Actual Dose  
 Start date 28 Jan 2021 End date 29 Jan 2021 Duration 1 Days apx  
 Dose 1 ml per Frequency Dose (text)  
 Time to onset first dose 3 Hours apx Time to onset last dose (Text)  
 Route subcutaneous Site of Admin Left Shoulder Administered by Attending Vet Data is for recommended dose   
 Exposed to concentrate prior to dilution

Experience  
 Reason for use LOE reason Number of patients associated apx  
 Was product used correctly?  Has patient had this product before?  When / details  
 Misuse type(s)  Dosage  Indication  Intentional Has patient reacted to this product before?  When / details  
 Has vet seen similar reaction before?  Details  
 Attending veterinarian's level of suspicion Possible/Medium - B

Batch / Lot Details  
 Product Lot # Expiry date 20 Jul 2022 Product investigation requested  

Prod Lot No	Qualifier	Expiry Date	Inv Req	Serials (Prod / Dil)
		20 Jul 2022	No	412652 /

Product Defects  
 Serials: Product - 412652

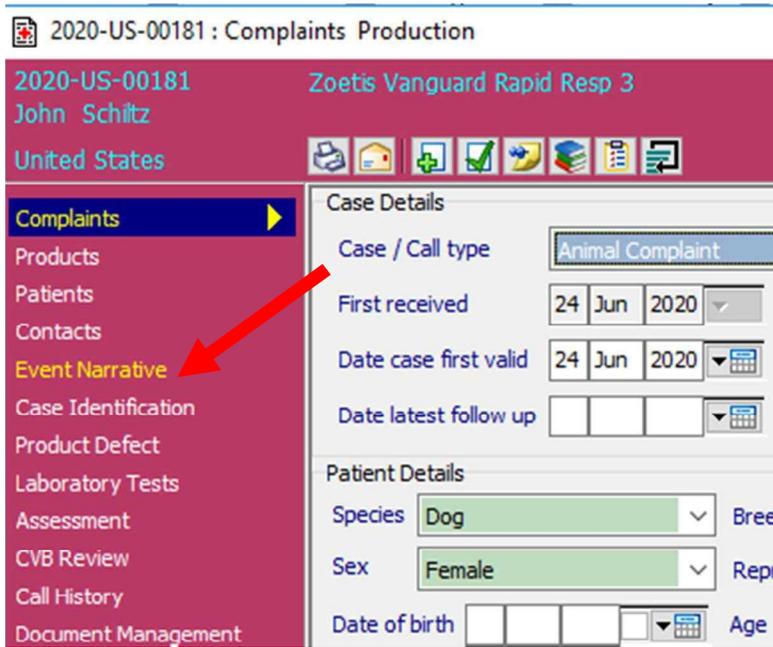
Generic / Brand Name	Start Date	End Date	Duration
Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterin / Not given	28-Jan-2021	29-Jan-2021	1 Days
Canine Influenza Vaccine, H3N2 & H3N8 / Killed Virus (Zoetis VANGUARD CIV)	28-Jan-2021	29-Jan-2021	1 Days

Audit Trail is on Audit scope is not set

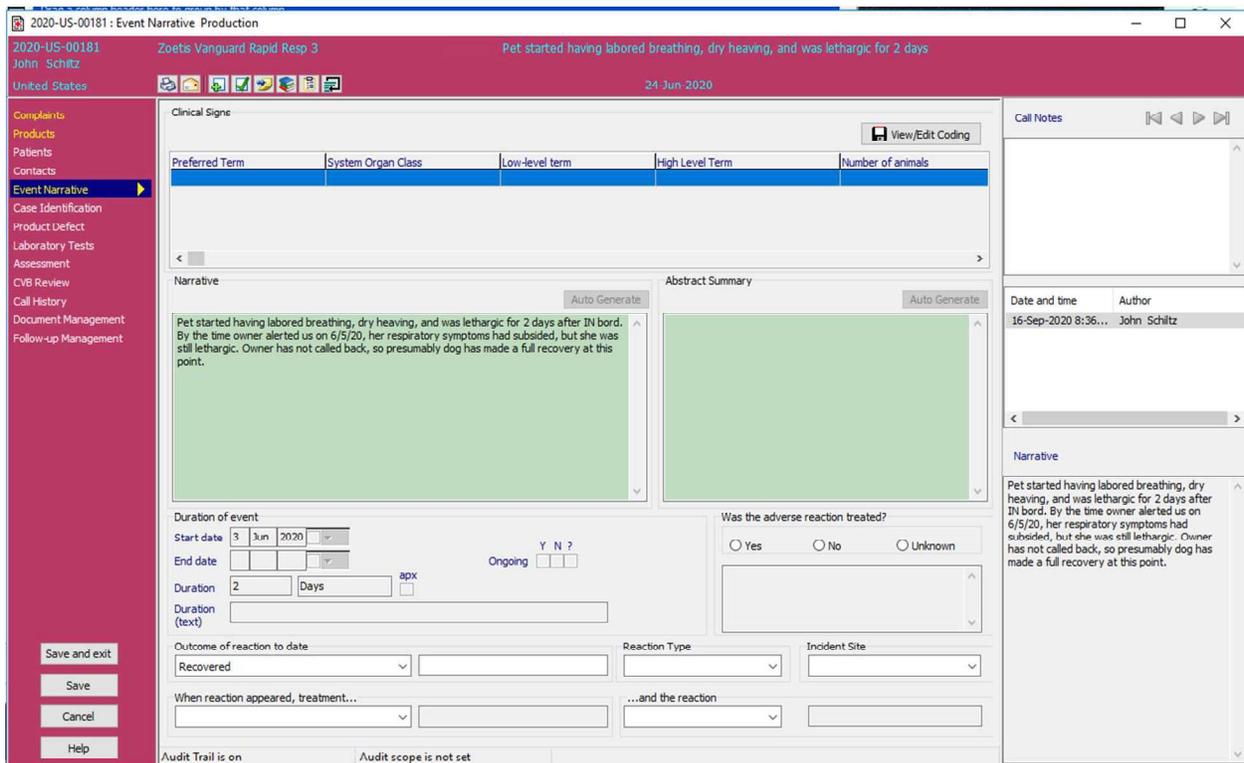
Save and exit Save Cancel Help

### VeDDRA Coding a Case:

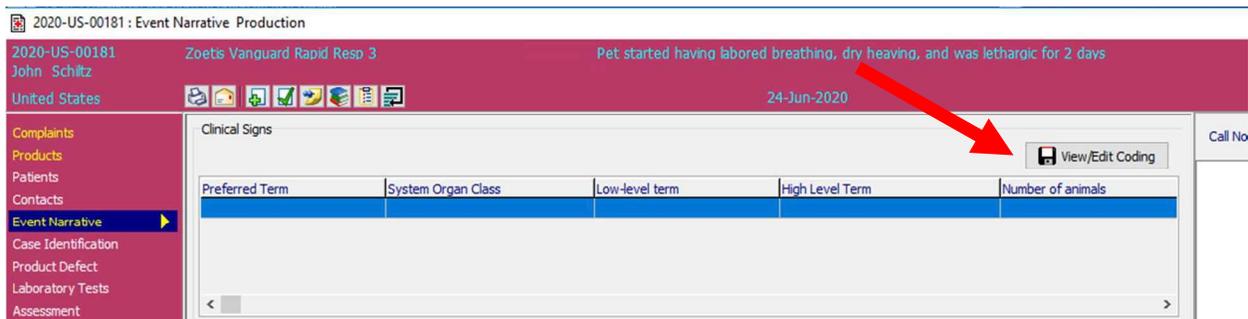
To VeDDRA code a case, select the Event Narrative screen from the left menu as shown here:



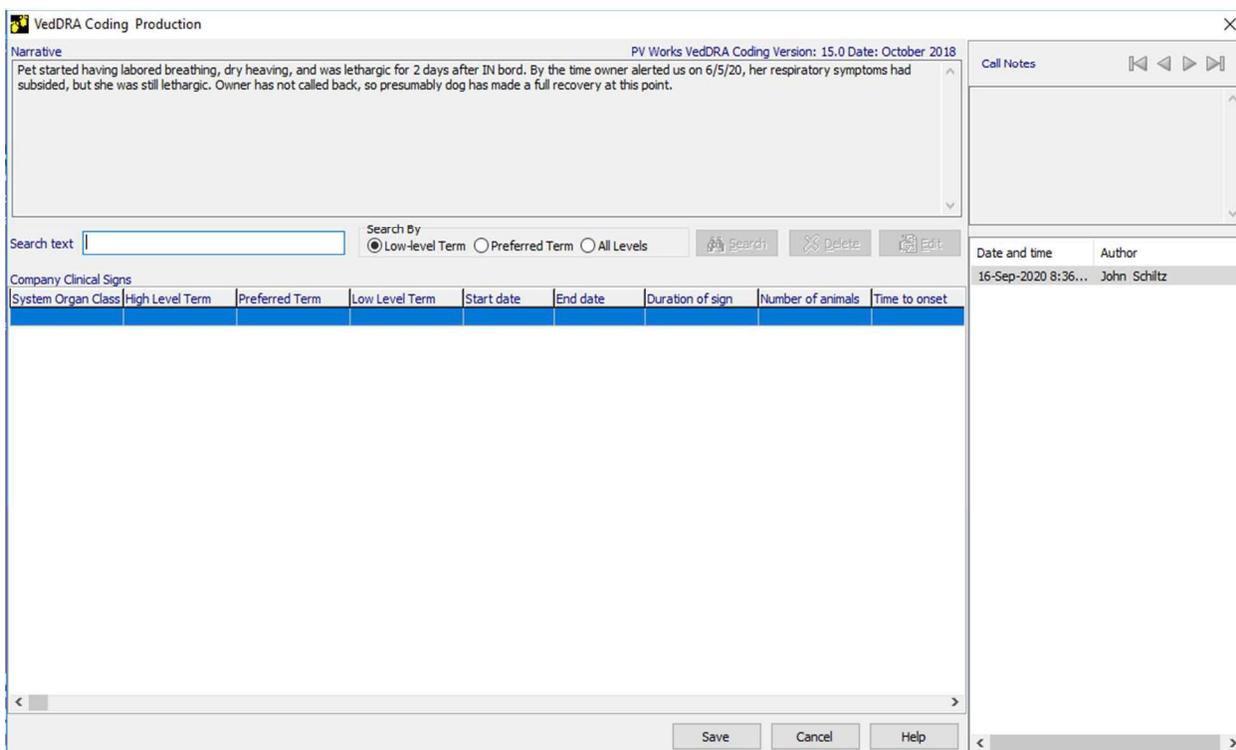
The Event Narrative Screen will appear as follows:



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:

VedDRA Coding Production

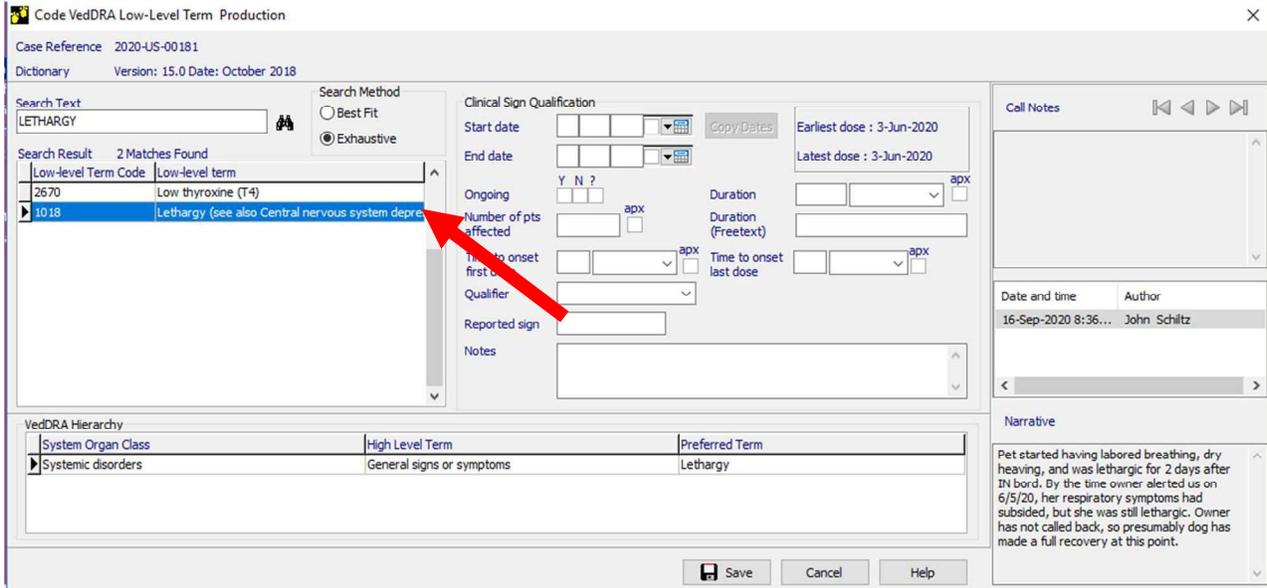
Narrative PV Works VedDRA Coding Version: 15.0

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 s  
subsided, but she was still lethargic. Owner has not called back, so presumably dog has made a full recovery at this point.

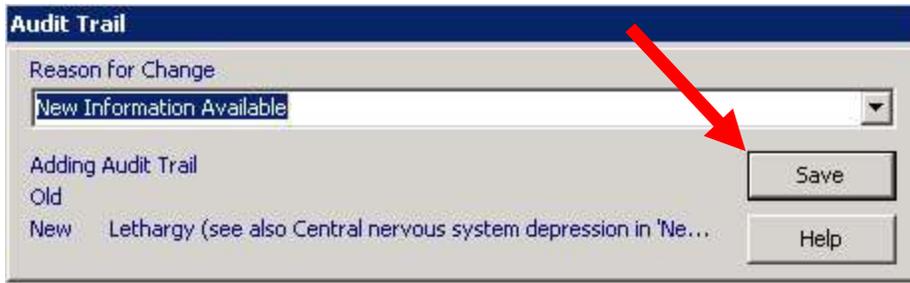
Search text  Search By  Low-level Term  Preferred Term  All Levels  

CVB-WI-0124.02

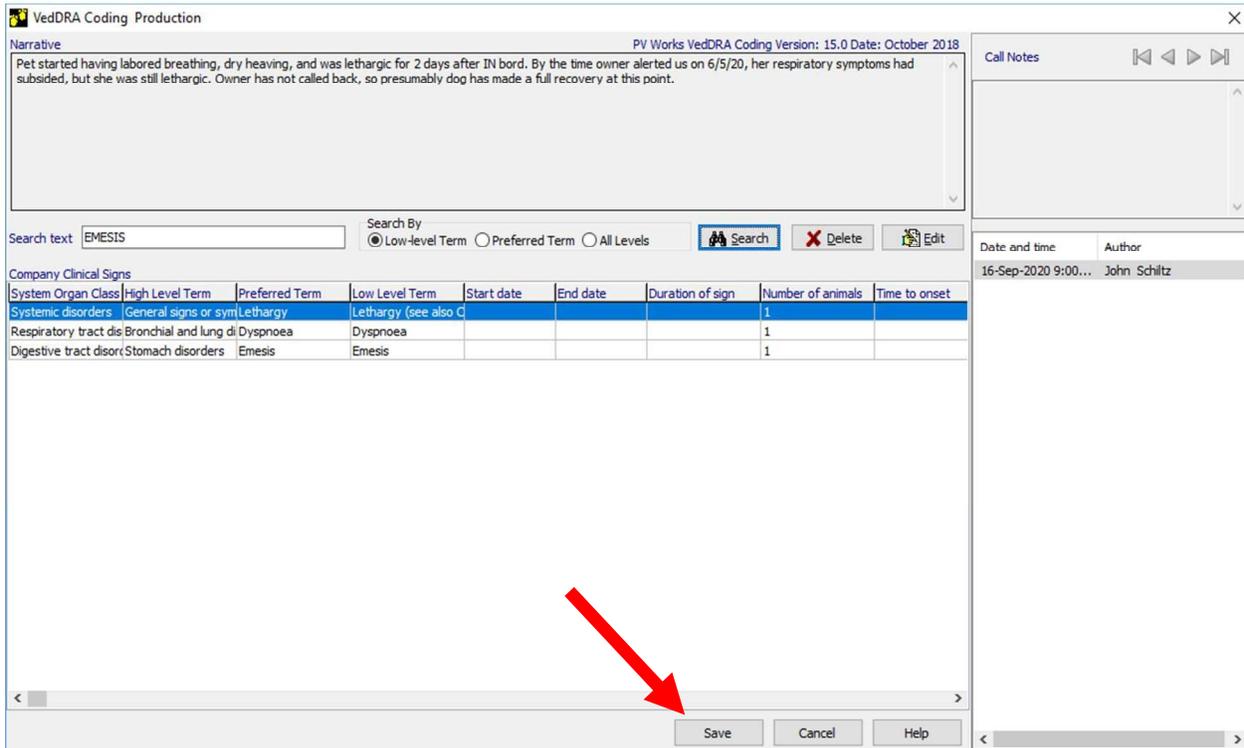
Select the respective Low-level term in the search result field as shown below:



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.



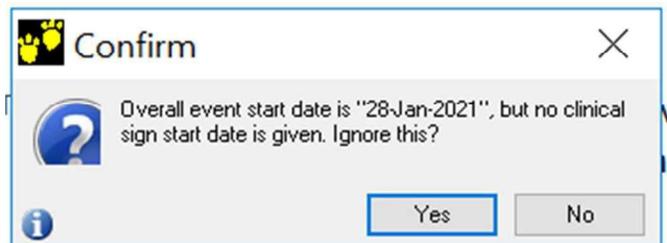
When the list of codes are complete for the case, save the VedDRA coding screen:



If the following message appears, select NO:

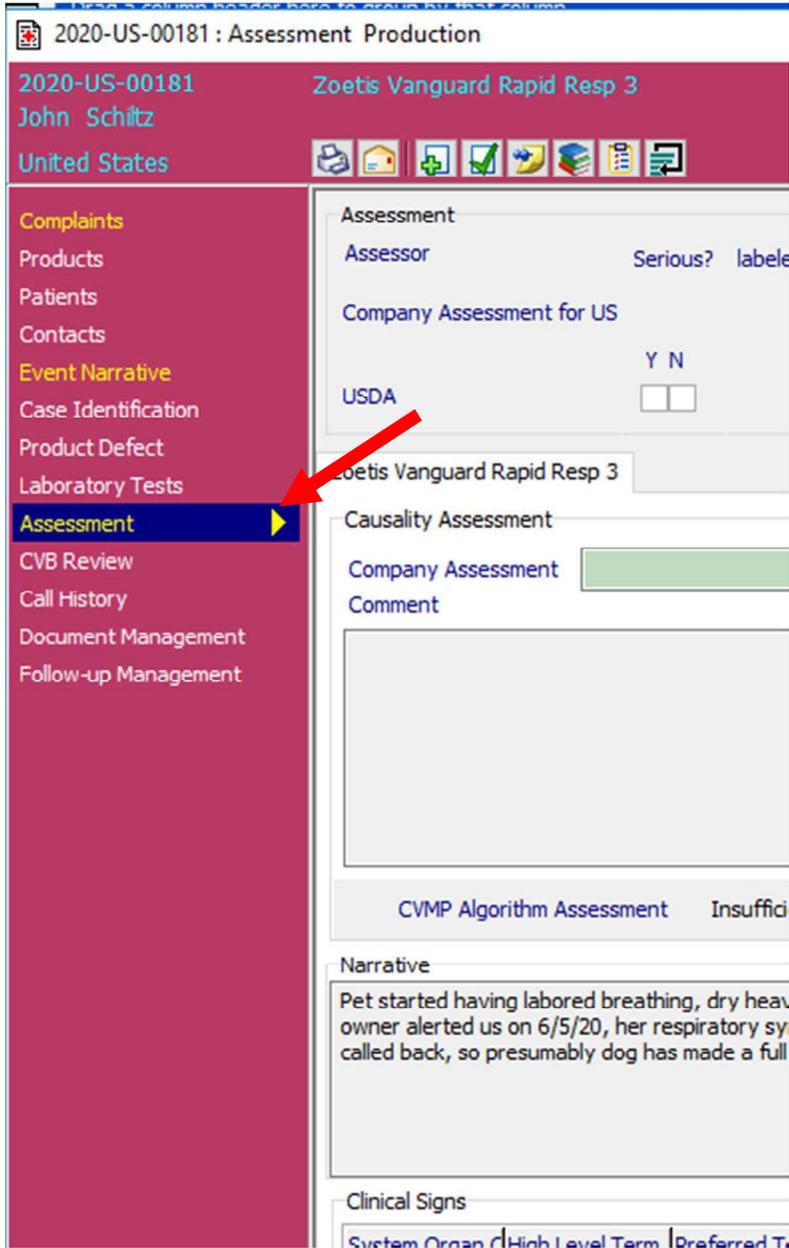


If the following message appears, select YES:



## 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.

The screenshot displays the 'Assessment' form in the PV-Works system. The form is for a case involving 'Zoetis Vanguard Rapid Resp 3'. The 'Company Assessment for US' field is currently empty, and the 'USDA Assessment' field is set to '0 / 1 / 2'. Two red arrows point to these fields, indicating where the user should provide the ABON assessment. The 'Narrative' field contains the following text: '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 symptoms had subsided, but she was still lethargic. Owner has not called back, so presumably dog has made a full recovery at this point.'

It is not necessary to assign causality for the VeDDRA terms.



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.

The screenshot displays the CVB Review screen. On the left sidebar, the 'CVB Review' link is highlighted. The main form area includes the following fields:

- USDA Administration: Document type / MA number (USDA Report, 9999), Submission type (Annual Report, DUMMY), Package type (ADE, 1), Purpose type (Voluntary report received electronically), Problem types (Adverse reaction;), Reportability (Voluntary report rec)
- Triage / Review History: Report received (24-Jun-2020), Registered on (24-Jun-2020), Database entry on (24-Jun-2020), Assigned reviewer (Migration), Reviewed on (Migration)
- Initial: Final Actions / Review outcome (AWAITING REVIEW, Reviewed as complete), No More Information Expected (checked), Close case after review (unchecked)

At the bottom, a table lists the case details:

Document id	Submission id	Package id	Received on	Report	Status
U9999	ADUMMY	A1	24-Jun-2020	Initial	Case entered into database

On the right side, there is a 'Date and time' field (16-Sep-2020 9:00) and a 'Narrative' section with the text: 'Pet started having heaving, and was IN bord. By the tir 6/5/20, her respir. subsided, but she has not called bac made a full recove'.

Complete the CVB review by returning to the Complaints screen and mark the case as Reviewed by selecting the checkmark as shown below:

2021-US-03319 : Complaints Production

2021-US-03319  
Rick Dewald  
United States

Not given  
K9 Coronavirus

Patient came in for Leptospirosis 1 year (SC RF) and Influenza 3wk (SC LF). Rece

17-Mar-2021

Case Details

Case / Call type: Animal Complaint  
Information type: Confirmed AE report  
Source: Technician / Receptionist

First received: 17 Mar 2021  
Case owner: Rick Dewald  
Country: United States

Date case first valid: 17 Mar 2021  
Responsible: Rick Dewald  
Method: PVX (Public)

Date latest follow up: [ ] [ ] [ ]  
Call recipient: Migration

Patient Details

Species: Dog  
Breed: Shih Tzu  
ID name: Papu Burago  
Patient #: 1 of 1

Sex: Male  
Repro status: Intact  
Female phys: [ ]

Date of birth: [ ] [ ] [ ]  
Age (from): 7  
Month(s): [ ]  
Age (to): [ ] [ ] [ ]  
Age (text): [ ] [ ] [ ]  
Weight from: 11.400 to [ ] Pounds

Product Details

Product: Not given 2668.00 190 - Zoetis Inc.  
Product Role: Suspect product  
Product #: 1 of 2

Start Date: 28 Jan 2021  
End Date: 29 Jan 2021  
Ongoing: [ ]  
Product Serial #: 424998B

Product Lot #: [ ]  
Expiry date: 16 Nov 2021  
Lot qualifier: [ ]  
Diluent Serial #: [ ]

Notes

Call Notes: [ ]  
Standard Complaint: [ ]

Narrative  
**Max length exceeded**  
Patient came in for Leptospirosis 1 year (SC RF) and Influenza 3wk (SC LF). Received both with no issues. Vaccination reactions were gone over with the owner. About 3 hours later owners called stating that the patient has been laying down and not wanting to

Standard Conclusion: [ ]

Conclusion: [ ]

Complaint types

Reviewed  
 Verification complete

No more information expected

Save and exit  
Save  
Cancel  
Help

Note: If the “Reviewed” option above the “Verification complete” is not visible, click the magnifying glass sign (circled below) and it will appear.

Suspect product Product # 1 of 1

Product Serial # 467390C

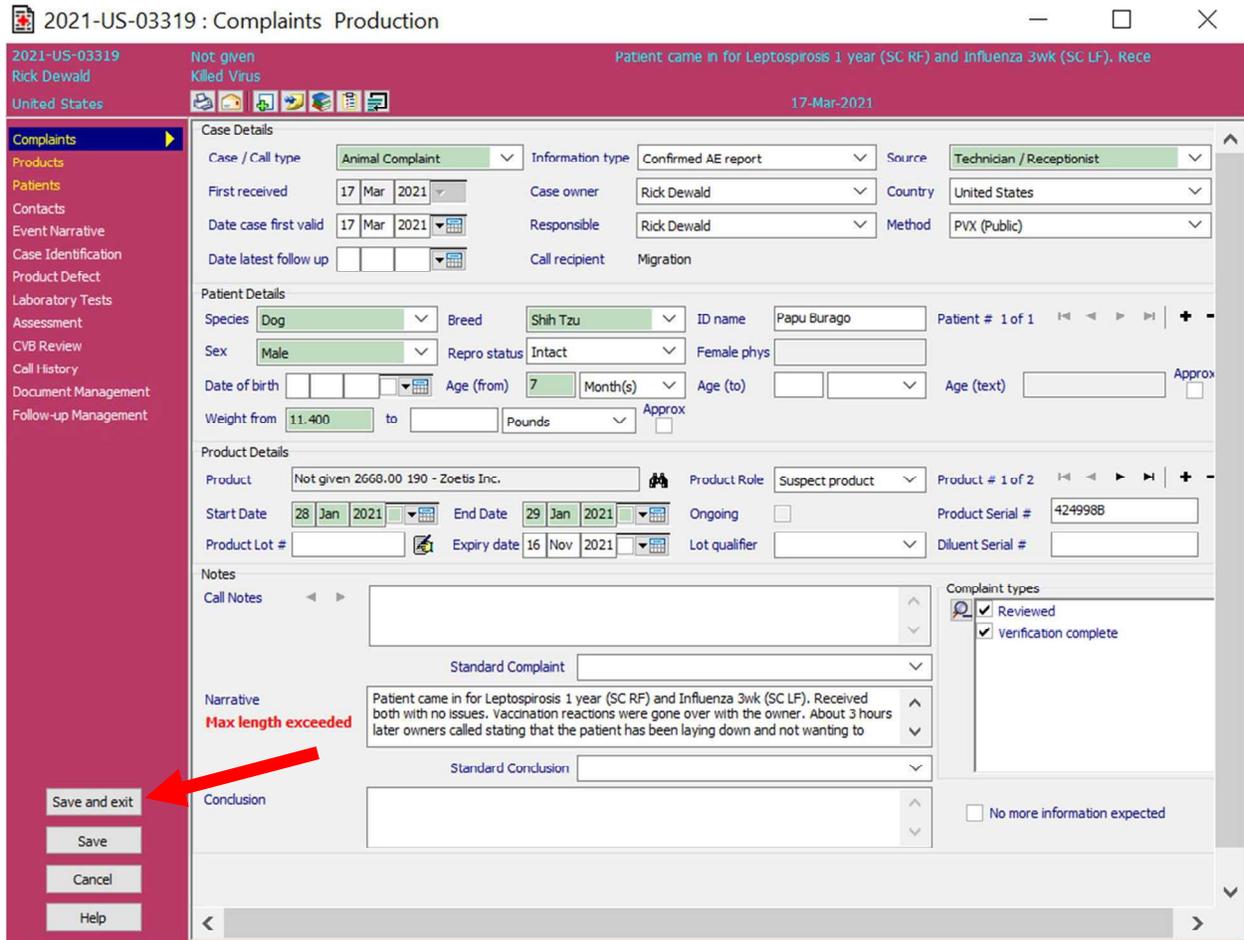
Diluent Serial # [ ]

Complaint types

Verification complete

No more information expected

To close the case, select Save and exit, as shown below:



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

