

Instructional Guidance for PV Express II for Public Submissions

NOTE: If you provide Personal Information when you submit an Adverse Event Report:

If you choose to provide us with personal information as in an email to one of our online email boxes, or by filling out a form with your personal information and submitting it to us through our website, we use that information to respond to your message and to help us get you the information you have requested. We do not collect personal information for any purpose other than to respond to you. We collect personally identifiable information (name, email address, or another unique identifier) only if specifically and knowingly provided by you. We only share the information you give us with another government agency if your inquiry related to that agency, or as otherwise required by law. Moreover, we do not create individual profiles with the information you provide or give it to any private organizations. We do not collect information for commercial marketing.

The PV Express II web-based form is the approved electronic method the public may use to submit individual adverse event reports (AER) for veterinary biological products to the Center for Veterinary Biologics (CVB). The PV Express II web-based form can be accessed [here](#). The other approved methods the public may use to submit adverse event reports to the CVB is through hard copy submissions (email, mail, and fax).

The step-by-step instructions provided in this guidance document are to aid the public in completing the PV Express II web-based form.

NOTE: ALL FIELDS on the PV Express II web-based form should be completed if known by you. All date fields appear on the form as European dates (DD-MM-YYYY). To delete a case already submitted, contact CVB.

NOTE: Please consider reporting your adverse event report to the biological manufacturer. As of February 17, 2021, manufacturers are required to report all adverse event reports they receive to the CVB. If the case you are reporting has already been submitted to the manufacturer, there is no benefit to also filing the case with the CVB.

Should you have any questions, need assistance or need to report system problems, please contact CVB.Pharma@usda.gov or at (515) 337-6100.

<https://cvbvp.aphis.usda.gov/PVXClient/index.html>

URL to initiate an adverse event report.

Help USDA Adverse Event Reporting

-----WARNING-----

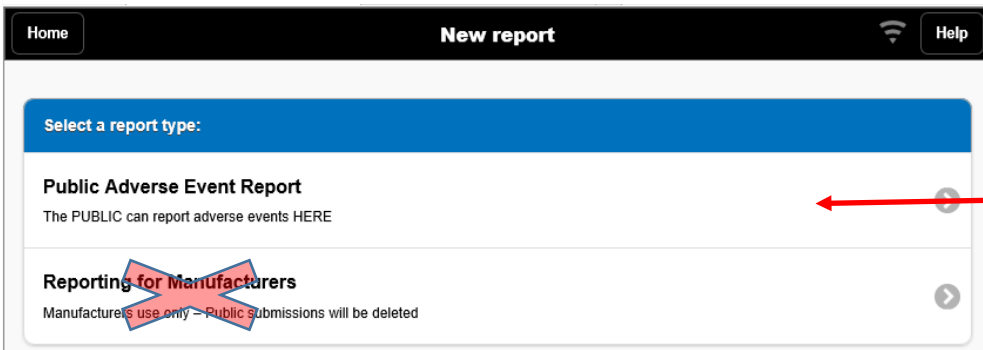
Upon Clicking the Submit Button You Agree to the Following Information: - You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only. - Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties. - By using this information system, you understand and consent to the following: 1. You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, the government may for any lawful government purpose monitor, intercept, search and seize any communication or data transiting or stored on this information system. 2. Any communications or data transiting or stored on this information system may be disclosed or used for any lawful government purpose. 3. Your consent is final and irrevocable. You may not rely on any statements or informal policies purporting to provide you with any expectation of privacy regarding communications on this system, whether oral or written, by your supervisor or any other official, except USDA's Chief Information Officer.

Click Here To Submit a Report to the USDA

Start the AER by clicking here.

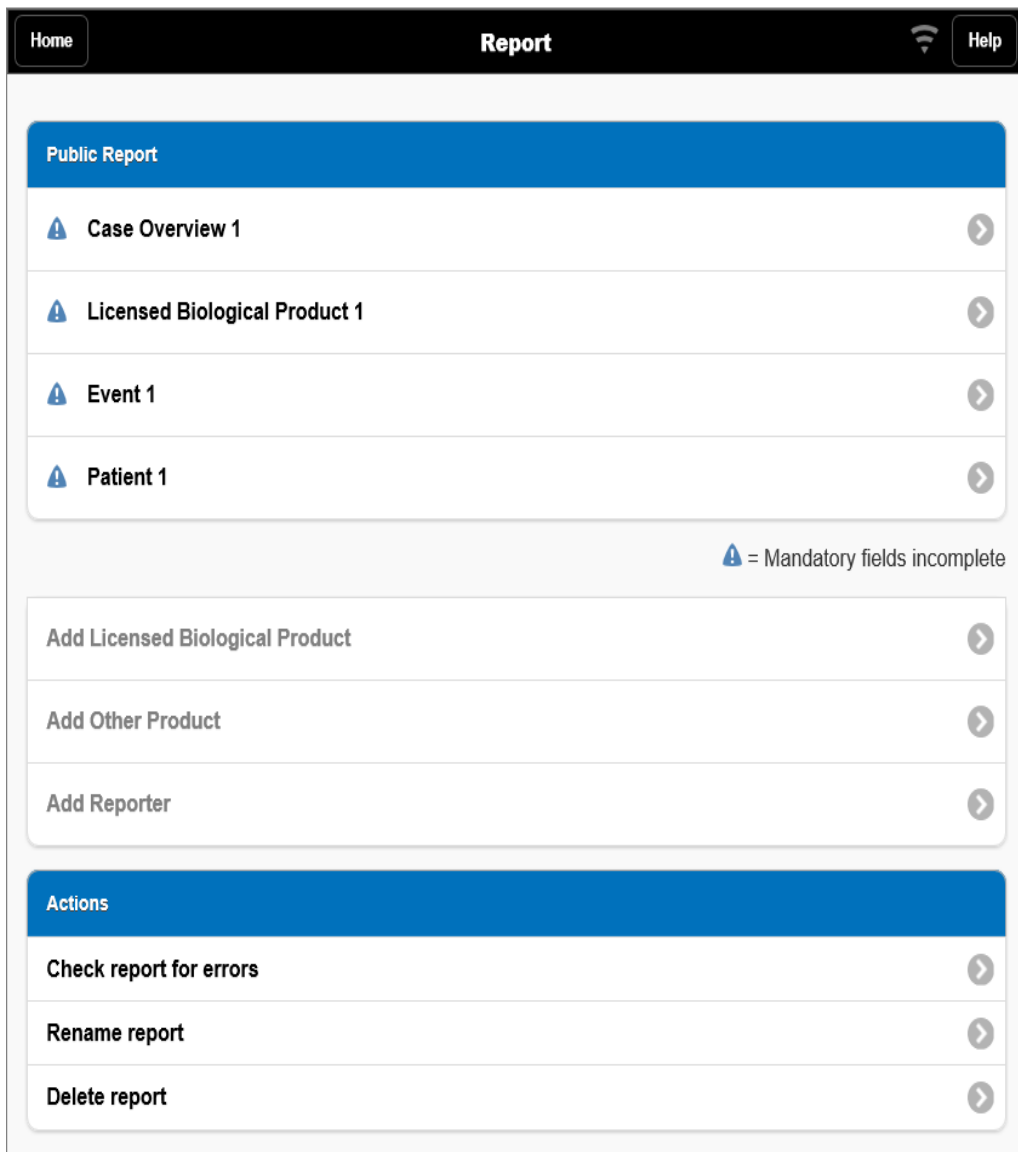




Then, clicking here.



Click on the Public Adverse Event Report.

NOTE: Do NOT use the "Reporting for Manufacturers" link as your entry may be deleted.



These 5 sections contain mandatory and optional requirements. Once the mandatory items are completed, the icon preceding the section name will change (eg.  or ). Instructions for completing each section will be covered in this document.

These 4 sections allow for the reporting of additional products and reporters.

This final grouping allows you to check the report for errors, rename the report, or delete the report.

Case Overview 1: This is the screen as it initially appears. Mandatory fields are denoted with red asterisks (*). Remember, fill in ALL fields if they are known to you. Some fields have default values, which can be changed by selecting the down arrow at the right of the field. The down arrows at the right end of each field reveals a drop-down list to choose from.

The screenshot shows a mobile application interface for a 'Case Overview' form. At the top, there is a black header bar with 'Save & close' on the left, 'Case Overview' in the center, and 'Cancel' on the right. Below the header, the form contains several fields:

- 'Country of occurrence:*' with a dropdown menu showing 'United States'.
- 'Case type:*' with a dropdown menu showing 'Animal Complaint (adverse event in animal(s))'.
- 'Submitted to Manufacturer?:' with a dropdown menu.
- 'Enter the Manufacturer's case number (if applicable):' with a text input field.
- 'Manufacturer's Case #:' with a text input field.
- 'Sender information' section with a red border around the 'Sender:*' dropdown menu.
- 'First name:' with a text input field.
- 'Last name:' with a text input field.
- 'Sender Company (if applicable):' with a text input field.
- 'Address 1:' with a text input field.
- 'Address 2:' with a text input field.
- 'City:' with a text input field.
- 'State:' with a text input field.
- 'Zip:' with a text input field.
- 'Country:' with a dropdown menu showing 'United States'.
- 'Phone:' with a text input field.
- 'Fax:' with a text input field.
- 'E-mail:' with a text input field.

At the bottom of the form, there is a large blue button labeled 'Save and close'.

The next picture shows the fields completed:

Save & close **Case Overview** **Cancel**

Country of occurrence:*

Case type:*

Submitted to Manufacturer?:

Enter the Manufacturer's case number (if applicable):

Manufacturer's Case #:

Sender information

Sender:*

First name:

Last name:

Sender Company (if applicable):

Address 1:

Address 2:

City:

State:

Zip:

Country:

Phone:

Fax:

E-mail:

Save and close

The Country of Occurrence field defaults to United States

The Case Type field defaults to Animal Complaint. If necessary, you can select symptomatic human case.

Has the case been reported to the vaccine manufacturer? Select yes or no.

Enter the establishment-assigned AER case number, if known.

Choose from the drop-down list an appropriate reporter role, usually 'Owner/Producer/Employee' or 'Attending Veterinarian.'

This section should contain information about the reporter, in this case Jim Smith.

Once all information is entered, click "Save and close." **Note** you can click here or on the top left corner of the screen.

Licensed Biological Product 1: This screen is as it initially appears. Enter information on this screen for your Establishment's licensed product involved in this adverse event report. The down arrows at the right end of each field reveals a drop-down list to choose from.

Save & close **Licensed Biological Product** **Cancel**

Product Identification

Enter details of the veterinary biological product/veterinary vaccine here.

Product role:*

Select the Licensed Establishment then the Product Code. If the product code is unknown, select 'Other':

Licensed Establishment:

Product code:

Serial number:

Trade name (Brand name):

Generic (True name):

Expiration date (DD-MM-YYYY):

Product usage

Problem type: **Adverse reaction**

Was product used as per label instructions?:

Off-label use type:

Has patient received this product before?:

Has patient experienced adverse events from this product before?:

Route of administration:

Site of administration:

Dose information

Start date (DD-MM-YYYY):

End date (DD-MM-YYYY):

Dose amount:

Dose unit:

Time between administration and event:

Units:

Who administered the product?:

Attending Vet's level of suspicion:

Save and close

Save & Close **Licensed Biological Product** **Cancel**

Product Identification
Enter details of the veterinary biological product/veterinary vaccine here.

Product role:

Select the Licensed Establishment then the Product Code. If the product code is unknown, select 'Other':

Licensed Establishment:

Product code:

Serial number:

Trade name (Brand name):

Generic (True name):

Expiration date (DD-MM-YYYY):

Product usage

Problem type:

Was product used as per label instructions?:

Off-label use type:

Has patient received this product before?:

Has patient experienced adverse events from this product before?:

Route of administration:

Site of administration:

Dose information

Start date (DD-MM-YYYY):

End date (DD-MM-YYYY):

Dose amount:

Dose unit:

Time between administration and event:

Units:

Who administered the product?:

Attending Vet's level of suspicion:

Save and close

Choose a Product Role, usually 'Suspect product.'

Establishment and Product Code for the product involved with this adverse event report. The Licensed Establishment information is available on the product label or from your veterinarian.

True name, Trade name, Serial number (if known) and expiration date of the product. This information is available on the product label or from your veterinarian. **NOTE** - expiration date is in European format.

Problem Type will usually be 'Adverse reaction.'

Choose the most appropriate response to these questions from the drop-down list.

Choose the route of administration and the site on the animal where administered.

Start date = date of administration. End date is used when vaccination extends over a period of time (vaccinating 500 calves over two days, for example). If part of a series of immunizations for an individual animal, please explain in the case narrative.

If this value is less than 1 (<1), you must enter a zero followed by the decimal, for example "0.5".

Enter the attending veterinarian's assessment of causality, if known.

Once all information is entered, click "Save and close." **Note** you can click here or on the top left corner of the screen.

Event 1: This screen is as it initially appears. Enter information on this screen to describe the actual adverse event. Provide a complete, detailed narrative. The down arrows at the right end of a field reveals a drop-down list to choose from.

The screenshot shows the 'Event' form with the following fields:

- Suspected Adverse Event Date(s):**
 - Date of onset of event (DD-MM-YYYY):*
 - Date is approx.:
 - Duration of suspected adverse event:
 - Duration unit: (dropdown arrow)
- Detailed Description of the Event (Narrative):**
 - What was the final outcome?:* (dropdown arrow)
 - Description of the event (Narrative):*

A blue 'Save and close' button is at the bottom.

The screenshot shows the 'Event' form with the following data and annotations:

- Suspected Adverse Event Date(s):**
 - Date of onset of event (DD-MM-YYYY):* 08-03-2021 (Annotation: The date the adverse event started.)
 - Date is approx.:
 - Duration of suspected adverse event: 4 (Annotation: How long did the adverse event last?)
 - Duration unit: Days (Annotation: Click the drop-down arrow and select an outcome from the drop-down list.)
- Detailed Description of the Event (Narrative):**
 - What was the final outcome?:* Recovered (Annotation: Click the drop-down arrow and select an outcome from the drop-down list.)
 - Description of the event (Narrative):* Fluffy was vaccinated for Rabies at the All Pets Vet Clinic, Anywhere, USA, on March 8, 2021. Within 4 hours of vaccination, the Rabies injection site had swelled to approximately 1" x1" and was firm to the touch. Fluffy was also limping on the right rear leg. The swelling receded over the next 4 days and the limping improved after a couple of days. Fluffy has returned to normal activities. (Annotation: Provide a complete, detailed description (narrative) of the adverse event.)

A blue 'Save and close' button is at the bottom. (Annotation: Once all information is entered, click "Save and close." Note you can click here or on the top left corner of the screen.)

The date the adverse event started.

If there is uncertainty about the date that the adverse event started, check this box.

How long did the adverse event last?

Click the drop-down arrow and select an outcome from the drop-down list.

Provide a complete, detailed description (narrative) of the adverse event.

Once all information is entered, click "Save and close." Note you can click here or on the top left corner of the screen.

Patient 1: This screen is as it initially appears. Enter patient information. The down arrows at the right end of a field reveals a drop-down list to choose from.

Save & close **Patient** **Cancel**

Animal Information

Species:*

Breed:

Mixed with:

Mixed breed:

Animal Name/ID:

Gender:*

Status:

Age:

Units:

Weight:

Weight unit:

Condition of animal prior to use of product:

Summary Information

No. of animals exposed:*

No. of animals reacted:*

No. of dead animals:*

Numbers are approximate:

Save and close

The screenshot shows a 'Patient' form with the following sections and fields:

- Animal Information:**
 - Species: * (Dropdown: Dog)
 - Breed: (Dropdown: Lhasa Apso)
 - Mixed with: (Checkbox)
 - Mixed breed: (Dropdown)
- Animal Details:**
 - Animal Name/ID: (Text: Fluffy)
 - Gender: * (Dropdown: Female)
 - Status: (Dropdown: Neutered)
 - Age: (Text: 2)
 - Units: (Dropdown: Week(s))
 - Weight: (Text: 25)
 - Weight unit: (Dropdown: Pounds)
 - Condition of animal prior to use of product: (Dropdown: Excellent)
- Summary Information:**
 - No. of animals exposed: * (Text: 1)
 - No. of animals reacted: * (Text: 1)
 - No. of dead animals: * (Text: 0)
 - Numbers are approximate: (Checkbox)
- Buttons:** Save and close (at top left and bottom), Cancel (at top right).

Choose the appropriate species and breed from the drop-down lists.

If a mixed breed, check this box, and provide the other breed.

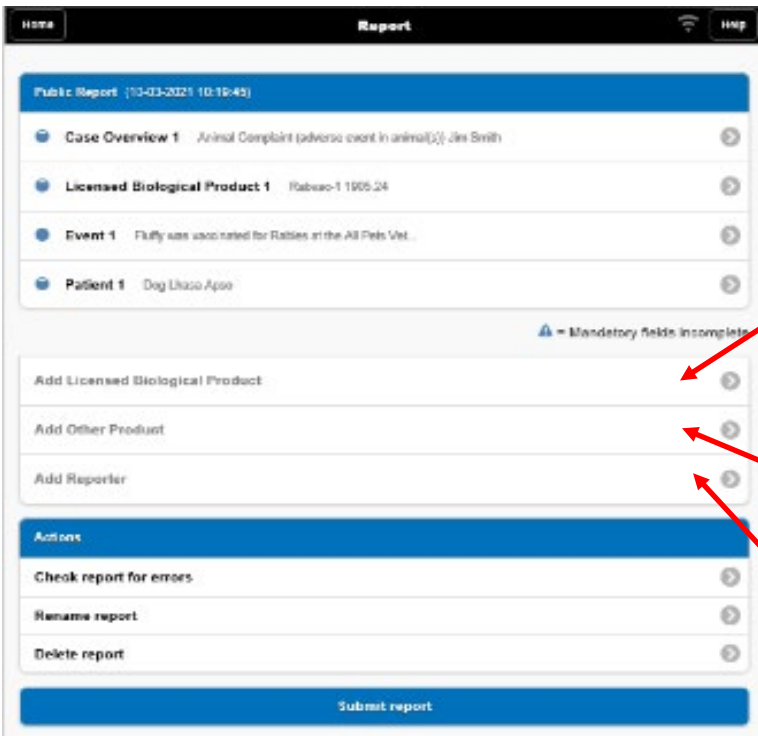
Provide the requested information regarding the animal.

Provide the number of animals exposed (vaccinated), the number reacted, and the number dead. If the numbers are approximations, check the box.

Once all information is entered, click "Save and close." **Note** you can click here or on the top left corner of the screen.

This completes the mandatory sections.

If necessary, add additional 'Licensed Biological Products' or 'Other Products' (such as pharmaceuticals, heartworm medication, or flea control products, for example).



For the additional licensed biological products that were administered, select “Add Licensed Biological Product” and follow the instruction for Licensed Biological Product. Remember to select “Suspect product” for the Product role field.

For any other products (pharmaceuticals, etc.) that were administered, select “Add Other Product” and complete all fields to the best of your ability.

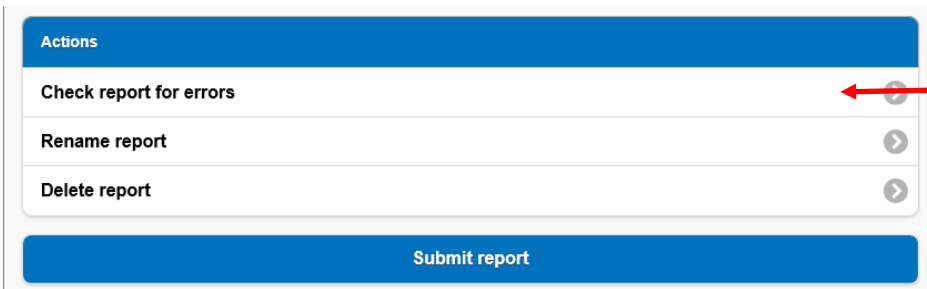
To add additional reporters (owner, vet clinic), select “Add Reporter.” See example below.

Select additional reporters from the drop-down list.

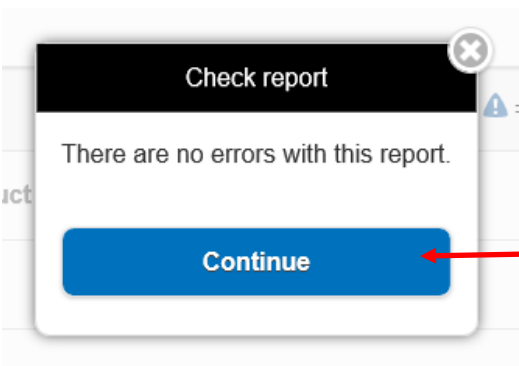
Fill out all the fields as completely and accurately as possible.

Once all information is entered, click “Save and close.” **Note** you can click here or on the top left corner of the screen.

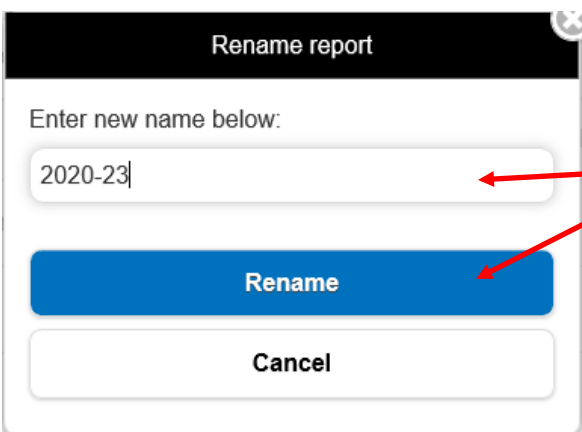
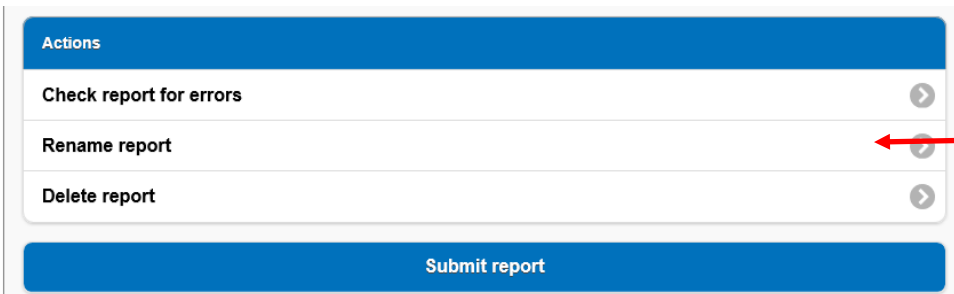
The final step involves checking the report for errors. If an error is found, you will be directed to correct the error and then allowed to submit the report.



If there are no errors, select continue:

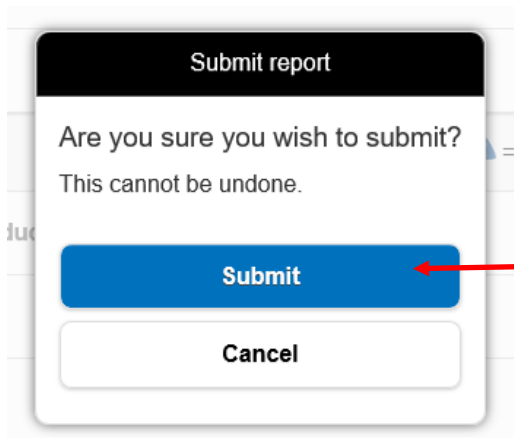
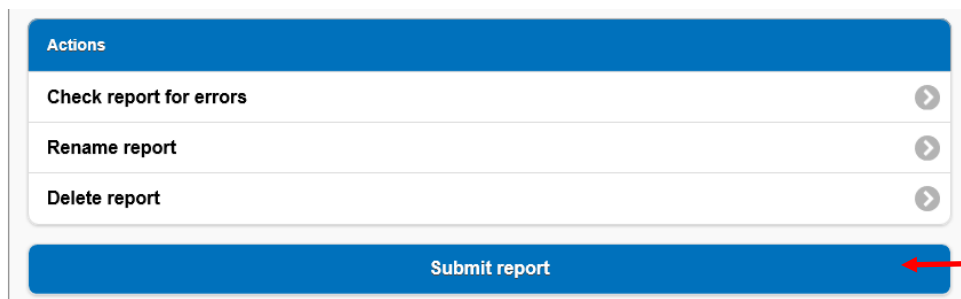


You can rename the report (not necessary).

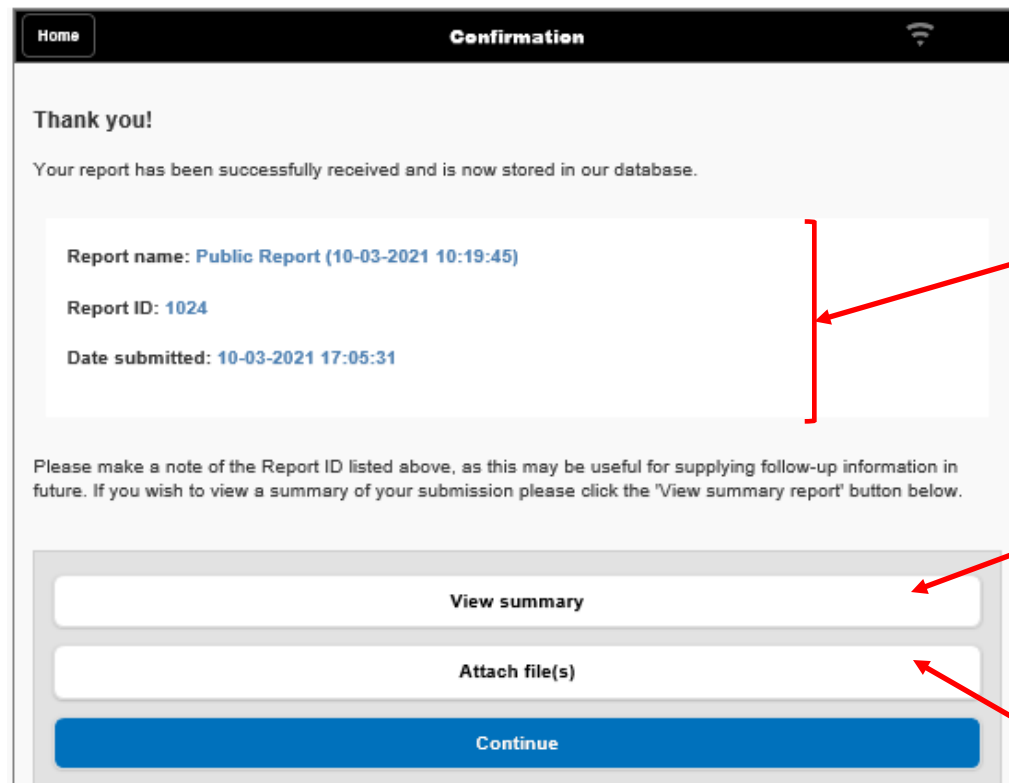


Enter a new name and then select "Rename."

Select "Submit report."



You will get a "confirmation" screen:



Note the Report default name is "Public Report" and the Report ID. The Report ID is a useful field for CVB to find your report.

Select View summary. This will allow you to see, save, and print the report. This provides documentation of the report.

Files can be attached to your report, such as veterinarian records, etc., if necessary.

Enlarged view of beginning of report.

PV-Express Report Summary
 PV-Express ID: 1024
 Submission date: 10 March 2021 05:05 PM

Patients
 Species: Dog
 Breed: Lhasa Apso
 Mixed with: N
 Animal Name/ID: Fluffy
 Gender: Female
 Status: Neutered
 Age: 2
 Units: Weekly
 Weight: 25
 Weight unit: Pounds
 Conditions of animal prior to use of product: Excellent
 No. of animals exposed: 1
 No. of animals infected: 1
 No. of animal deaths: 0
 Number are approximately: N

Reporters
 Primary reporter? Yes
 Gender: Other (Product/Employee)
 First name: Jim
 Last name: Smith
 Address: 155 Gains Drive
 City: Anytown
 State: IA
 Zip: 50005
 Country: United States
 Phone: (515) 555-5555
 E-mail: jsmith@nvet.com

Events
 Date of onset of event (DD-MM-YYYY): 04-03-2021 05:00:00
 Date is approx. N
 Duration of suspected adverse event: 4
 Duration unit: Days
 What was the final outcome? Recovered
 Description of the event (Narrative): Fluffy was used for studies at the AF Pet Vet Clinic, Anytown, USA on March 4, 2021. While in a room of vacuators, the Rabies Injection site had swollen to approximately 1 x 1/2 and was firm to the touch. Fluffy was also limping on the right rear leg. The swelling resolved over the next 4 days and the limping improved after a couple of days. Fluffy has returned to normal activities.

Products
 Product name: Suspect product
 Licensed Establishment: 106 - Biotech US Inc.
 Product code: 786234
 Serial number: 1234567
 Trade name (Brand name): Rabivac-1
 Generic (True name): Rabies Virus, Killed Virus
 Expiration date (DD-MM-YYYY): 01-01-2021 00:00:00
 Problem type: Adverse reaction
 Was product used as per label instructions? Unknown to Reporter
 Has patient received this product before? Unknown to Reporter
 Has patient experienced adverse events from this product before? Unknown to Reporter
 Route of administration: Intramuscular
 Site of administration: Right rear leg
 Start date (DD-MM-YYYY): 04-03-2021 00:00:00
 Dose amount: 1
 Dose unit: mL
 Time between administrations and event: 4
 Units: Hours
 Who administered the product? Attending Vet
 Attending Vet's level of suspicion: Possible/Infectious - B

Info
 Country of occurrence: United States
 NDBA/IDE (Public Reporting): Public
 Case type: Animal Complaint (adverse event) is animal(s)
 Submitted to Manufacturer? Yes
 Manufacturer's Case #: 2021-41234

Print summary report
 Email summary report
 Home

Summary report

PV-Express Report Summary
 PV-Express ID: 1024
 Submission date: 10 March 2021 05:05 PM

Patients
 Species: Dog
 Breed: Lhasa Apso
 Mixed with: N
 Animal Name/ID: Fluffy
 Gender: Female
 Status: Neutered

While too small to read in this picture, the summary contains all of the data you entered into the report.

Enlarged view of bottom of report.

Print summary report
 Email summary report
 Home

If desired, you can print the summary report for your records.

Finally, select “Home” to start a new report or exit the AER web-based reporting application.

