PV-Works Vet User Guide

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Table of contents

1 OVERVIEW 6
1.1 PV Works (vet) General Description 6
1.2 General Principles for Data Entry & Update 8
1.2.1 General Principles 8
Figure 1 - Screen Layout 8
1.2.2 How to Move around the system 9
1.2.3 Save & Exit, Save, Cancel and Help options 9
1.2.3.1 • Save & Exit 9
Figure 2 - Confirm & Save operation 10
1.2.3.2 • Save 10
1.2.3.3 • Cancel 10
Figure 3 - Cancel operation 11
1.2.3.4 Data Entry / Update Screen Styles 11
1.2.3.5 Simple Data Entry Screen Style 11
Figure 4: Data Entry : Simple Data Entry Screen Style 12

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1.2.3.6 Simple Data Entry Screen Style with multiple tabs 12
Figure 5: Data Entry: Simple Data Entry Style with Multiple Tabs 13
1.2.3.7 Multiple Record Data Entry Screen Style 13
Figure 6: - Multiple Record Data Entry Screen 14
Figure 7 - Confirmation of deleting a record 15
1.2.3.8 Multiple Record Data Entry Screen Style with multiple tabs 16
Figure 8: Data Entry : Multiple Record Data Entry Style with Multiple Tabs 17
1.2.3.9 Read Only Screens 17
Figure 9 - Read Only Screens 18
1.2.4 Case / Call Notes 18
1.2.5 Notes on Fields 19
1.2.5.1 How to add field notes 19
Figure 10 - Add/View Notes 19
Figure 11 - Notes Maintenance 20
1.2.5.2 How to View notes 20
1.2.5.3 How to Delete a field note 20
1.2.6 Dates 21
Figure 12: Elements of Date Entry 21
1.2.6.1 How to enter a Date from the keyboard 22
1.2.6.2 How to enter Dates using the calendar 22
Figure 13 - Calendar 23
1.2.6.3 How to erase a Date 23
Figure 14 - Deleting a date 23
1.2.7 Mandatory Fields 23
Figure 15: Mandatory Field 24
1.2.8 Spell-Checking Text 24
1.2.9 Toolbar Icons 24
2 STARTING PV WORKS 26
2.1 How to log on to PV-Works (Vet) 26
2.2 How to log out of PV-Works (vet) 27
3 PV-WORKS (VET) MAIN SCREEN 28
3.1 Drop Down Menu Options 29
4 ADVERSE EVENT CASE DATA ENTRY 31
4.1 Introduction 31
4.2 Creating a New Case 31
4.2.1 How to Create a New Case 32
4.3 Case number or identifier 33
4.4 Case Number Display 34
4.4.1 How to change the Case Number display 34
4.5 Assigning a workflow process 34

5 DATA ENTRY: ACTIONS FOR COMPLAINTS AND ENQUIRIES....35
5.1 Introduction....35
5.2 New Complaint / Enquiry....35
5.3 Handing Over Calls....36
5.4 Processing a Complaint....36
6 CODING....38
6.1 How to start Coding....38
6.2 VeDDRA Coding....39
7 DATA ENTRY AND ACTIONS FOR PRODUCT INVESTIGATIONS....45
7.1 Introduction....45
7.2 Creating an Investigation....45
7.3 Sending an Investigation to QA....46
7.4 Running an Investigation....46
7.5 Reviewing the results of the Investigation....47
8 FUNCTION KEYS....49
8.1 Menu Options....49
8.2 Moving between data entry screens and multiple records....49
8.3 Moving between fields and around the screen....49
8.4 Updating records....50
8.5 Editing Text....50
8.6 Help Keys & Exit....50
9 DATA REVIEW....51
9.1 How to Review your case....51
10 WORKFLOW PROCESSES....52
10.1 Case Level Workflow....52
10.2 The tasks assigned to me query / the to-do list....53
10.3 Completing Tasks on Save....53
10.4 Manager Level....54
10.5 Workflow Menu Options....55
10.6 Action Board Tasks....57
10.6.1 Creating an Action Board Task....57
10.7 Executing an Action Board Task....58
10.8 Managing Action Board Tasks....60
11 REPORTS....61
How to select a report from within a case.....61
11.1 Single Case Reports....62
11.1.1 How to use the Status Report Options....63
11.1.2 How to use Report Display Options....64
11.1.3 How to generate the report....65

11.2 Print and Print Preview Options 65
11.2.1 How to Preview a report 65
11.2.2 How to Print a Report 67
11.2.3 How to Save a report as an image to Disk 67
11.2.4 How to Send a report to Word 68
11.2.5 How to Send a report via the E-mail system 68
11.3 Report Approval 69
11.4 Create Regulatory Submission Function 69
11.4.1 Creating a submission of multiple cases 69
11.4.2 Recording a submission of multiple cases 72
11.5 Periodic Safety Update Report 73
11.5.1 Creating a PSUR 73
11.5.2 Recording a submission of a PSUR 74
12 LETTER WRITING 76
12.1.1 Creating Letters 76
12.1.2 How to select and print a letter template from the main screen 76
12.1.3 How to select and print a letter template from within a case. 76
12.1.4 How to edit the letter when it is created 77
12.2 Managing the Letter Queue 78
13 CASE MANAGEMENT 80
13.1 Selecting Cases 80
13.1.1 How to select a case by using the case mask 80
13.2 Main Screen Grid Querying 81
13.2.1 How to search for a case using main screen grid queries 81
13.2.2 How to search for a case using Build A Query 83
13.3 Find Case Button 86
13.3.1 How to use the Case Search Results Screen 87
13.4 Case Linking 88
13.4.1 How to Link Cases 89
13.4.2 How to Remove Linked Cases 91
13.5 Case Locking 91
13.5.1 How to Lock a case 92
13.5.2 How to Unlock a case 92
13.6 Case Versioning 93
13.6.1 How to Create a New Version for a case 93
13.6.2 How to select a Version 94
13.7 Delete Case 95
13.7.1 How to delete a case 95
13.8 Close or Re-Open a Case 96
13.8.1 How to Close or Re-open a case 96

14 DUPLICATE CHECK 97
14.1.1 How to use Duplicate Check 97
15 AUDIT TRAIL 100
15.1 Editing data with audit trail switched on 100
15.1.1 How to Edit Information with the Audit Trail active 101
15.2 Viewing the Audit Trail 101
15.2.1 How to view the Audit Trail 102
15.3 Audit Trail Report 102
15.3.1 How to use Audit Trail Report Options 103
15.4 Data Review with Audit Trail 104
15.4.1 How to Review your case with Audit Trail 105
16 HELP 106
16.1 PV-Works Help System 106
16.1.1 How to access the online help from the main screen 106
16.1.2 How to access the online help from the Data Update screens 106
16.2 Reporting Issues to Assured Information Systems Ltd 107

1 Overview

This document provides an introduction to PV-Works (vet) for new users. It is also a useful 'aide memoir' for more experienced users. The information contained in this guide is sufficient for users to start using the software. For more detailed explanations of the functionality of each module and for details of functionality deliberately omitted from this document, the reader is referred to the PV-Works (vet) Functional Specification.

The document refers to a person called the 'Systems Administrator'. This is an employee of your company who can configure PV-Works (vet), making changes to access rights, system options and so forth in order to tailor the system to meet local business needs. Such configuration can occur without reference to Assured.

1.1 PV Works (vet) General Description

PV-Works (vet) combines a commercial workflow product with flexible product safety functionality to produce an integrated application that meets both business and regulatory needs. The same software can satisfy the requirements of companies of all sizes ranging from international organisations with distributed databases through departmental systems to single users or in a mixed environment of any combination of system type.

PV-Works (vet) consists of several modules within a single application:

- Pharmacovigilance case entry and reporting
- Complaint and Enquiry management
- Product Defect Investigation management
- Process Control / Workflow

Each of these can be implemented or ignored as required by each customer and within a customer implementation can be assigned to individual users.

The process management module tracks individual cases through a series of process steps, which may be assigned on a case by case basis. The system supports multiple process templates allowing different processes to be applied to different case types. Individual users only see those cases that require their immediate attention and workload supervisors can review and re-assign the workload for individual users and workgroups. With the process data gathered, managers are able to measure actual performance against targets, allowing the identification of bottlenecks, over-allocated staff, under-tasked staff and training needs.

The design of the pharmacovigilance modules supports:

- international reporting requirements for single case reports and line listings from the key regulatory authorities world-wide
- easy to use, intuitive data entry and review screens that may be tailored to meet local business requirements
- multiple assessments by different staff at different times e.g. reporter, local company, corporate

The system is both flexible and efficient. A separate Systems Administration function allows selected staff to configure PV-Works (vet) to an individual customer's requirements. This includes defining specific code list data values, managing a list of company products and creating teams of users to be assigned to process tasks.

There is a separate functional specification for the Systems Administration tool.

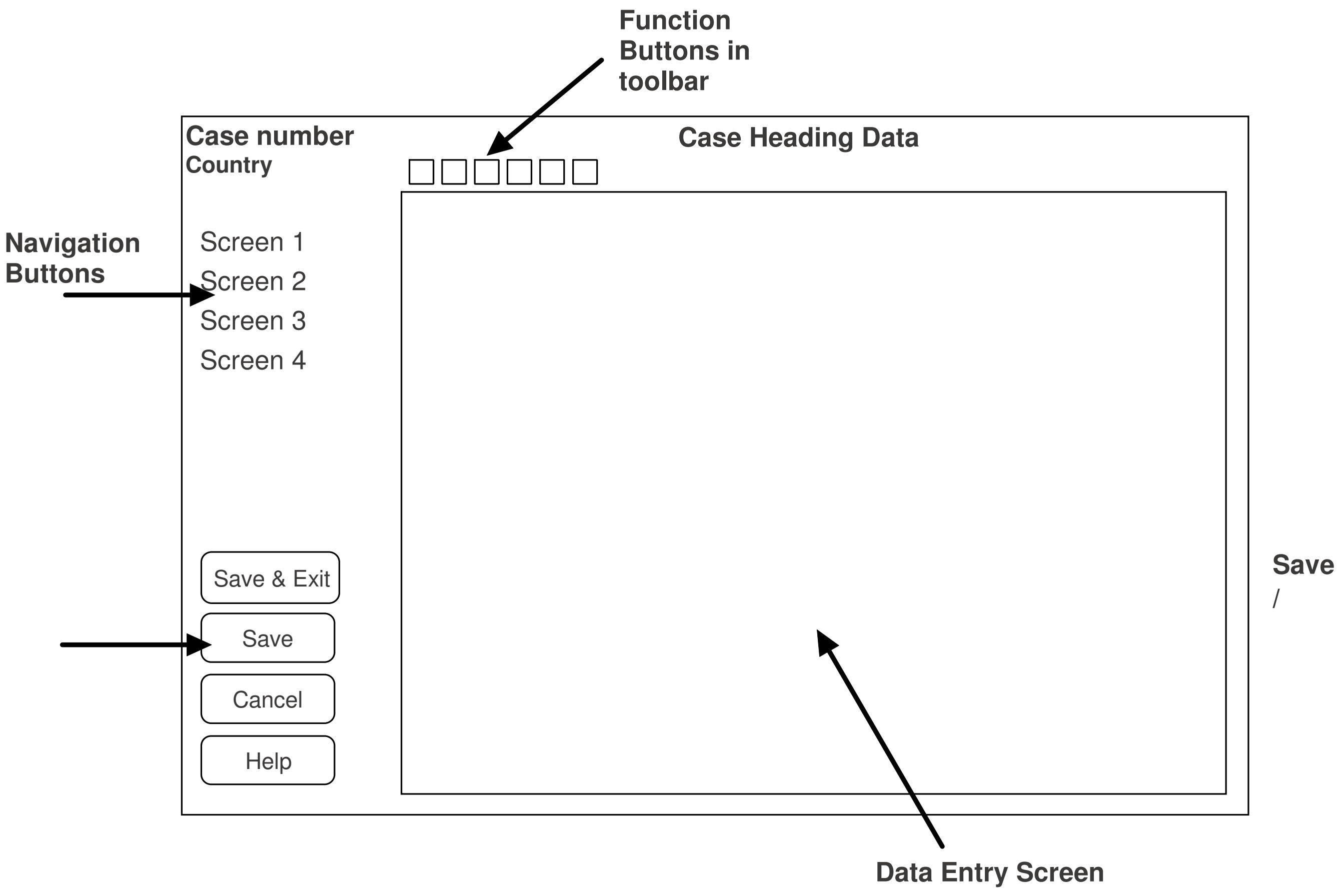
The PV-Works (vet) application and its Systems Administration tools are controlled by strict security functions that allow the administrator to control access to particular functions and to particular cases.

1.2 General Principles for Data Entry & Update

1.2.1 General Principles

PV-Works data entry, update and assessment screens follow the design shown in Figure 1 below.

Figure 1 - Screen Layout



Save / Cancel Buttons

The Navigation buttons on the top left-hand column of the screen are used to move between data entry and review screens.

The ‘Save’ and ‘Save & Exit’ buttons are used to save data to the database. The difference is that the ‘Save’ button leaves the user viewing the update screen after saving data, i.e. positioned for further editing, while ‘Save and Exit’ closes the edit session down so that the user may start a different task. Some users like to ‘Save’ data as they enter large amounts just in case there is a system failure – application or network. (That is not to say that PV-Works (vet) is prone to such failure, just that users hate to re-enter data!).

The ‘Cancel’ button returns to the main menu, discarding any unsaved amendments.

The Toolbar buttons allow the user to execute other functions against the selected case without the need to close it. These buttons duplicate functions found elsewhere in the menu system and are a convenient way to create reports or letters for instance from the active case. Holding the mouse on a toolbar button will reveal a text label that indicates the purpose of the button.

- ***Some toolbar buttons require that the case is saved before they can be executed. An example would be the ‘report’ button which requires the case data to be saved so that the report reflects the latest data.***

1.2.2 How to Move around the system

When the user first starts a Data Entry / Update session the above screen is displayed with the data entry screen window showing ‘Screen 1’. The navigation buttons ‘Screen1, Screen2’ etc may be clicked using the **left-hand mouse button** to change the display in the Data Entry window.

The user can display individual screens in any order and as many times as required during an editing session. When a screen has been displayed its title on the navigation area changes colour to indicate to the user that it has previously been shown.

Alternatively, the user may move from page to page in sequence using the **Page Up** / **Page Down** keys. Note that **Page Down** from the last screen will show the first screen and **Page Up** from the first screen will show the last screen. These screens should be thought of not as a list but a ‘ring’.

The order of the screens displayed in the Data Entry / Update functions are controlled by the System Administrator.

1.2.3 Save & Exit, Save, Cancel and Help options

The four save / cancel buttons at the bottom of the navigation bar have the following functions:

1.2.3.1 • Save & Exit

Saves all the data changes made since the last save (or the editing session began) and then will exit the Data Entry / Update function.

The user is returned to the screen that called the Data Entry / Update screen, typically either the Main Menu or the ‘to do’ list.

The Save & Exit function requires that the user confirms the save operation. See Figure 2 below. (See also Section 10, 'Workflow Processes', for further features of this pop up screen)

Figure 2 - Confirm & Save operation

The popup is for the first save of a new case. When saving changes to existing cases the 'Ad-hoc Process' button is available allowing processes to be added to the cases.

1.2.3.2 • Save

Saves all the data changes made since the last save (or the editing session began) but remains in the Data Entry / Update function. This Save function can be used during large edit sessions to reduce any risk of data loss due to system failure.

The Save function requires that the user confirm the save operation. See Figure 2 above.

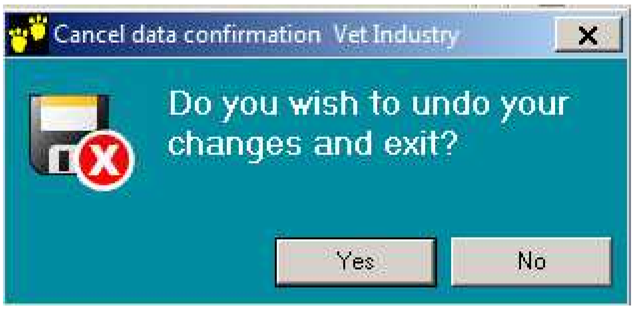
- ***By cancelling the Save or Save & Exit command all data entered since the last save (or the editing session began) is NOT saved to the database.***

1.2.3.3 • Cancel

Cancels all the data changes made since the last save (or the editing session began) and then exits the Data Update function. The user is returned to the screen that called the Data Update screen. Note that once data changes are saved by either of the two Save options above, they cannot be cancelled.

The Cancel function requires that the user confirms the Cancel operation. See below.

Figure 3 - Cancel operation



By cancelling the Cancel command, the user is returned to the data entry screen so that further entry can take place.

- ***The Cancel command does NOT erase any data saved during the edit session. For example, if a user has clicked 'Save' three times during editing, makes some more changes and then presses 'Cancel', only the last changes are ignored. Changes associated with the first 'three' saves in this example are kept. There is no function to wipe out all changes made in the whole editing session if the 'Save' button is used.***

- **Help**
  View the on-line help text.

1.2.3.4 Data Entry / Update Screen Styles

There are four basic types of data entry screen:

1. Simple Style where all data fields are displayed in a single window
2. Simple Style with more than one screen. Each screen is displayed on a separate tabbed record card
3. Multiple Record Style where a case has several records holding similar information eg contacts, regulatory reports.
4. Multiple Record Style with more than one screen. Each screen is displayed on a separate tabbed record e.g. patient.

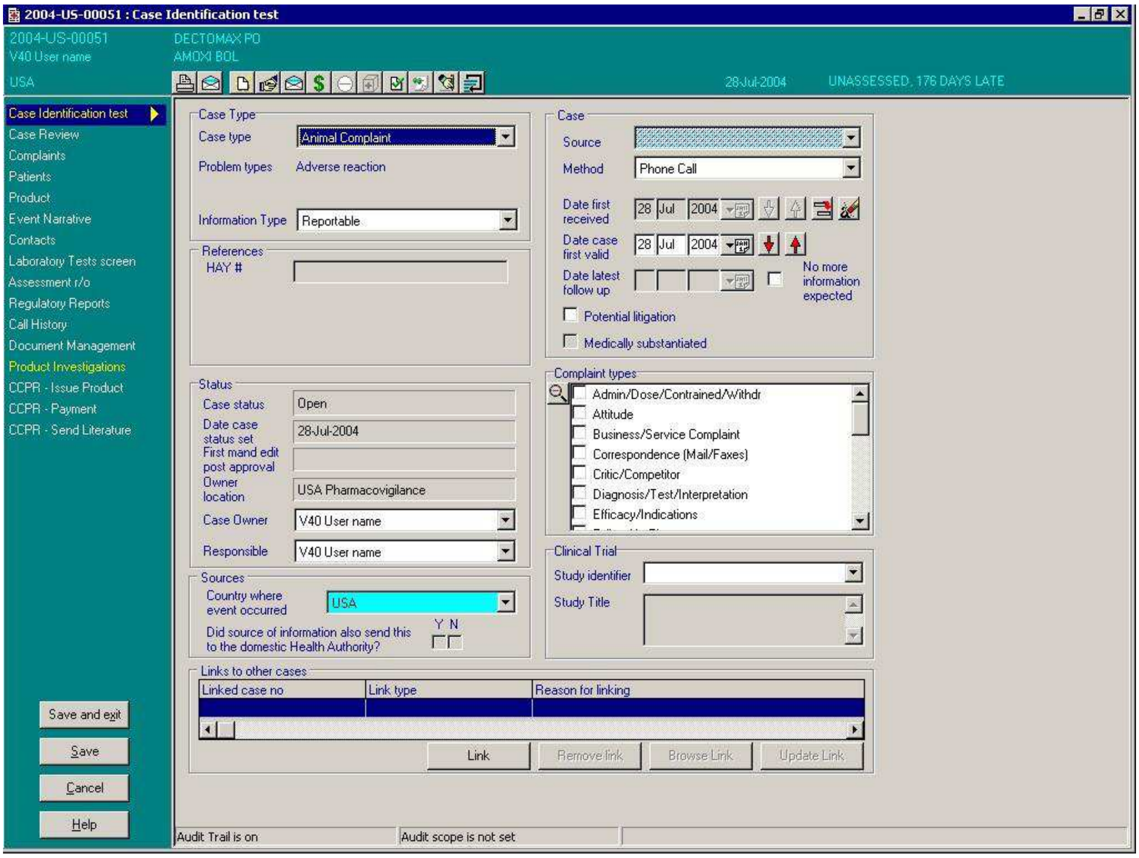
These are described in the next two sections.

1.2.3.5 Simple Data Entry Screen Style

Simple data entry screens either display all their data in a single window or in a single window with pop-up windows for additional information.

An example of this screen type is 'Case Identification' (see Figure 4). This screen summarises some of the key definition data for the case e.g. problem type, date received, case validity and country of occurrence. In a case this data can only occur once.

Figure 4: Data Entry : Simple Data Entry Screen Style

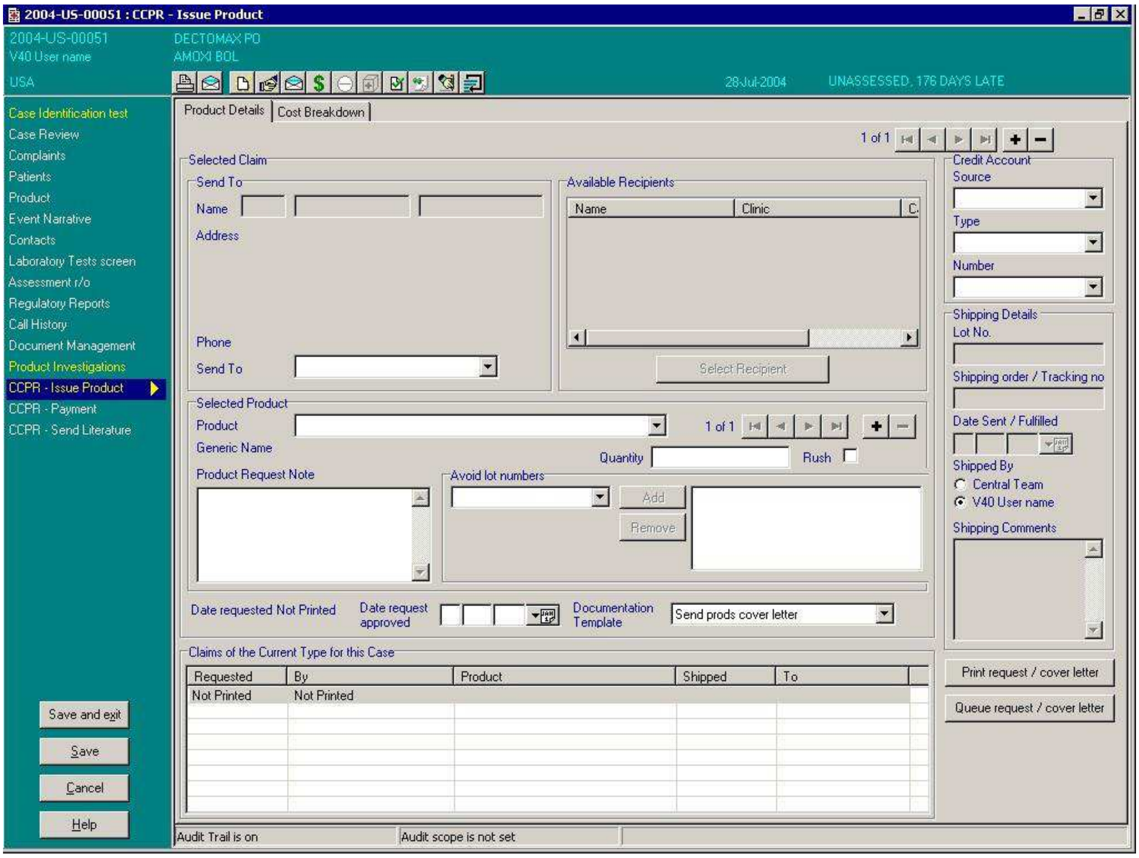


1.2.3.6 Simple Data Entry Screen Style with multiple tabs

An extension of the simple screen style above is where several screens are linked together using a 'tabbed record card' style to allow the user to navigate easily between related data items.

The screen for complaint product issue data in Figure 5 is a typical example. On the product issue screen the user may enter details of the customer and the product(s) to be issued and on the cost breakdown screen may enter the internal cost codes to which the cost of this product will be assigned. These two 'sets' of data are related under a common heading of 'Issue Product' and are accessed using standard Windows record cards (i.e. tabbed records).

Figure 5: Data Entry: Simple Data Entry Style with Multiple Tabs

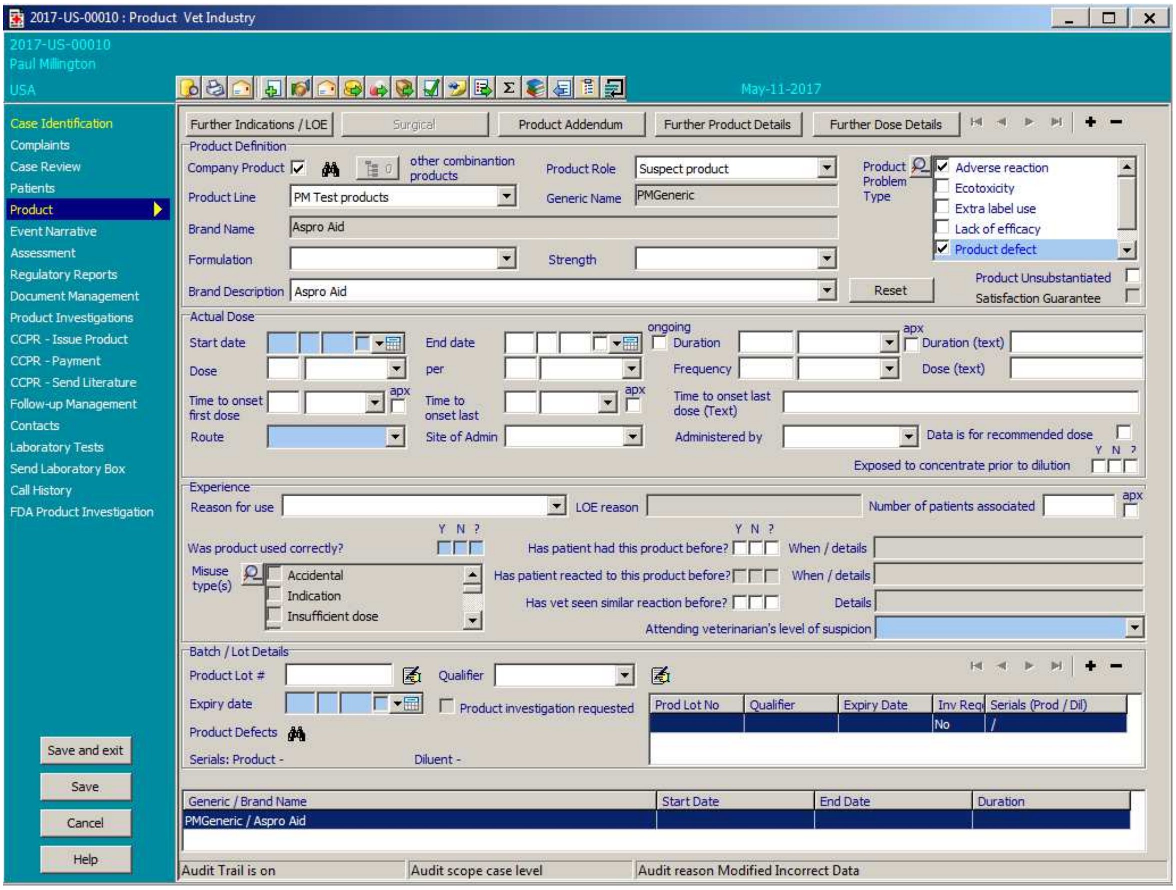


1.2.3.7 Multiple Record Data Entry Screen Style

Some data types may occur several times in a case and the number of occurrences in a case will vary. Examples of this type of record are laboratory tests, adverse events and products.

For these types a Multiple Record Data Entry Screen style is used as in the example shown in Figure 6.

Figure 6: - Multiple Record Data Entry Screen



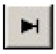
The screen shows the details for one entry, i.e. one adverse event, one product, one laboratory test etc. The screen in Figure 6 shows the data for one particular product. These data fields may be edited.

A list of the available data entries is shown in a 'Summary Grid' and typically this is shown at the foot of the screen. Each row in the summary grid represents an entry. The highlighted row (shaded) denotes the record displayed in the area above the grid. The Summary Grid data may not be edited directly, only by changing their values in the 'display data' section.

These sections act as navigation bars within the list. There are three methods that can be used to move between multiple records:

1. Via the VCR-style navigation bars
2. Using the keyboard
3. By clicking the left hand mouse button on the row in the Summary Grid that describes the record of interest

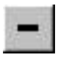
The keyboard commands and navigation bar symbols are used as follows:

Key	Operation	Comment
	Move to the first record	Or use “ctrl-Up arrow”
	Move to the previous record	Or use “ctrl-left arrow”
	Move to the next record	Or use “ctrl-right arrow”
	Move to the last record	Or use “ctrl-down arrow”

Amendment of these records is achieved via the buttons on the right hand side of the screen:

- - Add a new record

Click this button to create a new record. The system will display an empty pop up data template; or clears the display records to allow you to enter a new record. This is similar in operation to a simple data entry screen. Once data has been entered it is ‘saved’ to the Multiple Record format and appears as a new record at the bottom of the list.



- - Delete a record

Click this button to delete the selected record. The system asks you to confirm this action as shown in Figure 7 - Confirmation of deleting a record below.

Figure 7 - Confirmation of deleting a record

On some screens (note this is a minority) a third amendment button is displayed between the ‘add’ and the ‘delete’ button:

- - Edit a record

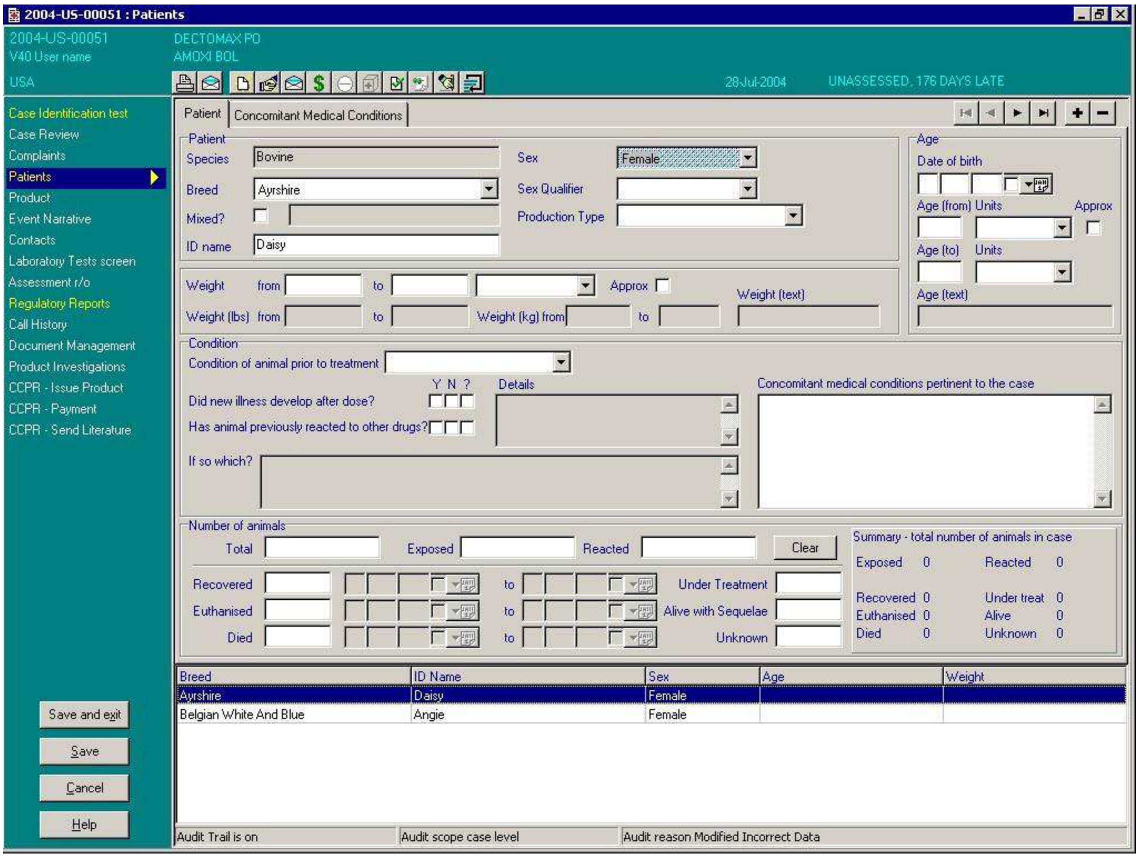
Click this button to edit the selected record. Normally this operation is not necessary as the selection of a record placed it into 'edit mode' automatically. However, where the decision to edit needs to be made more deliberate, the selected record may not be edited immediately and the user needs to click the edit button before amendments can be made. An example of this is the Call History screen.

1.2.3.8 Multiple Record Data Entry Screen Style with multiple tabs

An extension of the multiple record screen style above is where several screens are linked together using a 'tabbed record card' style to allow the user to navigate easily between related data items. This style is the least commonly used.

The screen for patient data in Figure 8 is a typical example. The patient screen is divided into two tabbed record cards, one for patient information and one for concomitant medical conditions. The patient record card has a multiple record style so that more than one patient of the same species may be entered. In this example multiple concomitant medical conditions are added via the second record tab.

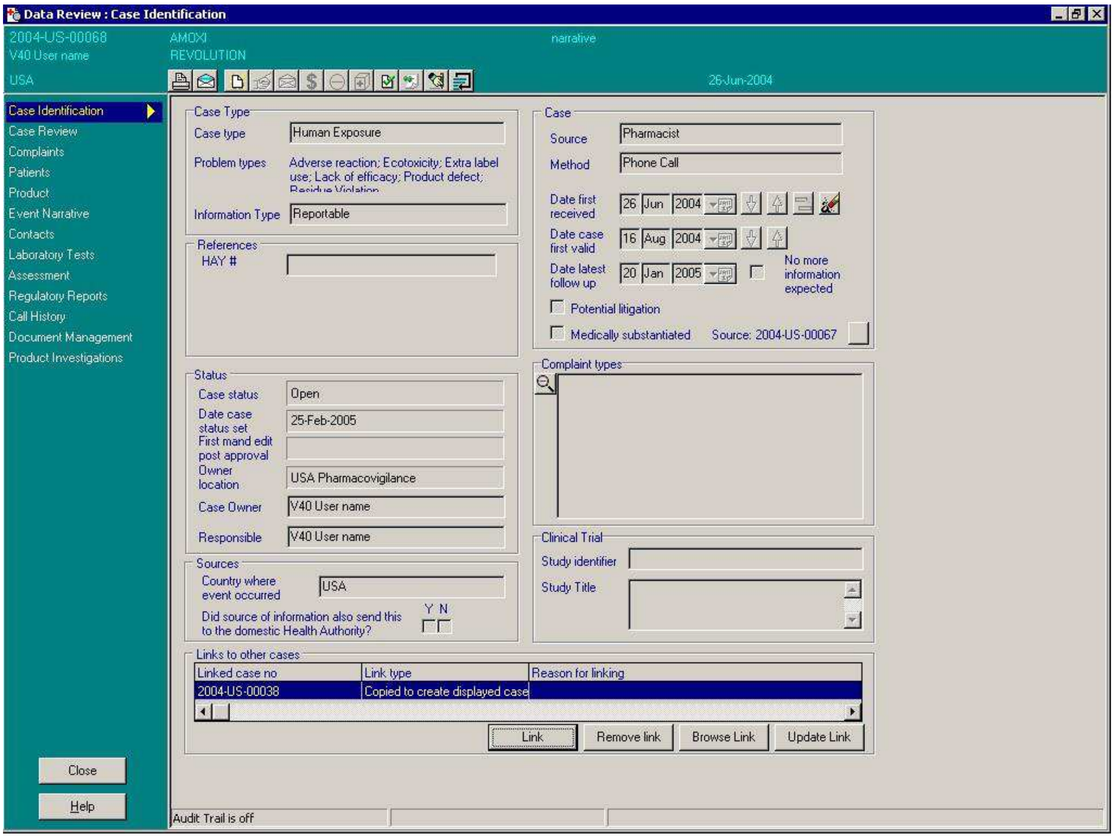
Figure 8: Data Entry : Multiple Record Data Entry Style with Multiple Tabs



1.2.3.9 Read Only Screens

Screens can be added to the list with ‘read only’ security so that data can be read but not altered; this option may be useful where data needs to be provided to support changes that will be made in other screens or where a user is only required to edit certain data items such as the assessment or clinical sign codes. For example, the sample screen shown in Figure 9 below is a 'read only' screen.

Figure 9 - Read Only Screens



1.2.4 Case / Call Notes

See also Notes on Fields, section 1.2.5.

Users may add internal working comments at a case (or call) level. These may be comments or questions passed from one person to another or additional information not held elsewhere in PV-Works (vet).

While these notes are not used in any regulatory report, they may be included in queries and internal reports and Assured believes that this information is 'discoverable' by regulatory authorities. As such customers are advised to create a policy on the contents of such notes.

The case / call note is added in a standard PV-Works (vet) screen named 'Call History'. This is a standard 'Multiple Record Data Entry Screen Style' as described in section 1.2.1. The Call History screen is found in the Data Update and Data Review functions.

Assured believes that this format of 'internal note' is simpler to use and easier to find than 'notes on individual fields' described in section 4.2.3. As such users are recommended to use the case level style.

1.2.5 Notes on Fields

See also Case / Call Notes, section 1.2.4.

Notes on fields are internal, working comments that may be made against any database field. They can contain additional information about the data item, internal company comments on the significance of the data or any other information that the user feels is pertinent. Such data may be extracted for internal reports if necessary.

No regulatory information is stored in notes. All descriptive text, which is required in a regulatory report (such as a case narrative), is held in a narrative field, which is part of the main data entry screens.

1.2.5.1 How to add field notes

The notes function is entered by:

1. Highlighting the field against which the note is to be made (by clicking its contents)
2. Right-clicking the mouse and selecting 'Add note' See Figure 10

Figure 10 - Add/View Notes

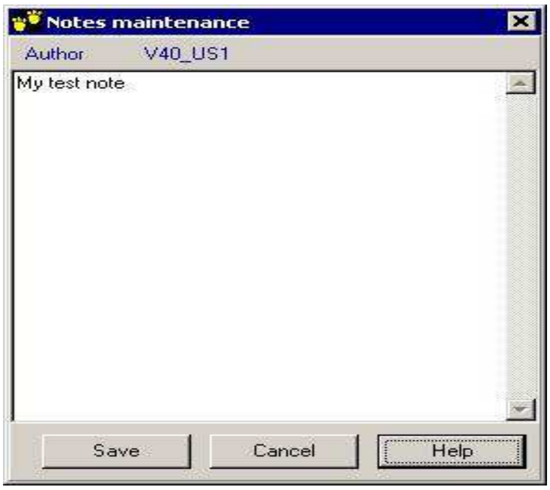
This function displays a pop-up box in which the user may add a comment or note. See Figure 11 below.

3. Type the note required
4. Once you have completed the notes text you can
   - select **Save** to save the information on this screen and return you to the previous screen
   - select **Cancel** to cancel the notes record and returns to the previous screen

✔ ***To Save a new note or changed note to the database you must also use the Save or Save and Exit buttons on the main screen***

The author's name, the date and time of creation and the field name against which the note is written are automatically saved.

Figure 11 - Notes Maintenance



1.2.5.2 How to View notes

All notes are displayed on the Call History screen. The purpose of this is to gather all notes into one place for easy review. Assuming that the user is granted appropriate security rights for the field note, the text may be edited via the Call History screen after it has been saved.

1.2.5.3 How to Delete a field note

1. Access the note on the Call History screen
2. Select the **Delete** button
3. The system will ask you to confirm the deletion, select **Yes** (see Figure 7 - Confirmation of deleting a record above)

✔ ***To Save the deletion to the database you must also use the Save or Save and Exit buttons on the main screen***

1.2.6 Dates

Dates entered into PV-Works (vet) are of two types:

- User entered, e.g. start of treatment, date case received
- System generated, e.g. date database record created, date of audited change.

Most system-generated dates are not visible to the user.

Both types of date are stored with four digit years.

While system generated dates are always known precisely, user entered dates can be either incomplete (partial) and/or approximate. For example, the start of treatment may need to be recorded as 'May 1998' or 'around 23 December 1997' or 'about June 2000'.

To achieve this all user-entered dates consists of four fields, both in the database and on all PV-Works (vet) screens. These are:

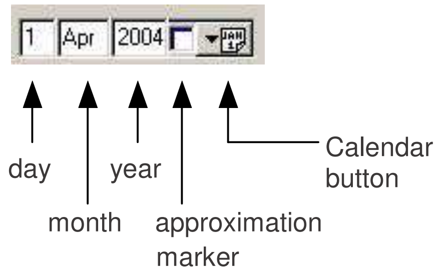
Day

Month

Year

Approximation flag

Figure 12: Elements of Date Entry

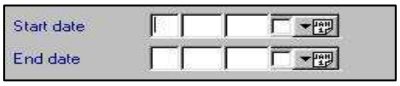


- ***The display of the date on PV-Works (vet) screens can be changed to Month, Day, Year by the System Administrator to support USA formats. This has no effect on the underlying data and both US and European approaches can be supported in the one single installation, i.e. this may be set at a user level.***

Dates can be entered either by typing directly from the keyboard or from a pop-up calendar.

1.2.6.1 How to enter a Date from the keyboard

1. Select the first field in the date.



2. The formats for entering dates are:

- Day: 01 or 1
- Month: 01 or JAN or jan or Jan
- Year: full year 1998 or two-character year only 98

✔ ***When a year is typed as two characters the century will default from the century valid for that date:***
✔ ***E.g. today's date 6-APR-99:***
✔ ***a date of birth entered as 12-Jan-57 will become 12-Jan-1957*** ✔ ***a date of birth entered as 15-Oct-00 will become 15-Oct-1900*** ✔

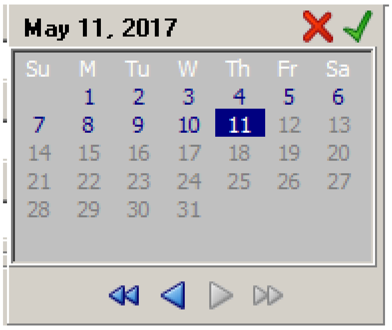
✔ ***Where the date will accept future dates e.g. batch expiry date***
✔ ***E.g. today's date 6-APR-99*** ✔ ***A batch expiry date entered as 12-Jan-99 will become 12-Jan-1999*** ✔ ***A batch expiry date entered as 12-Oct-01 will become 12-Oct-2001***
✔ ***RECOMMENDATION***
✔ ***The simplest (and quickest) method of date entry is to type six numbers. For example using the European system a date entered as 041204 on 29 March 2005 will be interpreted as 4 Dec 2004.***
✔
✔ ***Note that days and months less than 10 need to be expressed as two digits with a leading zero.***
✔
✔ ***Note that the month is entered as a number but is always displayed as three letters. This avoids confusion with the US / European date formats during case review.***

1.2.6.2 How to enter Dates using the calendar

The calendar function displays a pop up calendar, which allows the user to select the required date and allows the user to move between years and months via buttons.

1. Click the **Calendar** button  for the date field.
2. The calendar will appear as Figure 13 below
3. You can move around the months and years using the Previous Year, Previous Month, Next Month and Next Year arrows. 
4. Select the date you require and select the confirm option to return to the previous screen

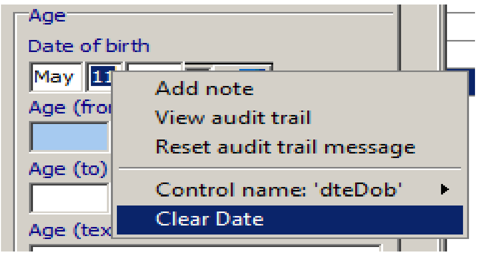
Figure 13 - Calendar



1.2.6.3 How to erase a Date

Dates can be erased from the screen display using an option available by clicking the right-hand mouse button. This is useful if the date is to be re-entered from the keyboard. See Figure 14 below.

Figure 14 - Deleting a date



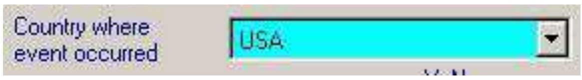
1.2.7 Mandatory Fields

The System Administrator may define certain fields as ‘mandatory’. These are typically set as the fields that are critical or important for reporting, e.g. the fields on a CVMP or FDA 1932 report. There are three basic types:

- Fields that must be present to save a new case; there are very few of these
- Fields that must be present in order to report a case to an agency
- Fields that ought to be present or considered for entry before the case is reported to an agency.

To help you during data entry the background of these 'special' fields is coloured as shown in Figure 15.

Figure 15: Mandatory Field



The System Administrator will determine the colour scheme for each type.

1.2.8 Spell-Checking Text

Most data is selected from look up lists, but where text is typed into boxes it may be checked for spelling accuracy. The Spell-Check function is accessed from the right mouse button and will check all text in the box where the cursor is placed. This function applies to all fields where free text entry is permitted.

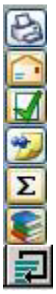
The functionality provided by this software is very similar in behaviour to the spellcheck in Microsoft Word.

Provided that suitable rights are given by the System Administrator, users can add their own terms to the dictionary. This is useful as the standard dictionary is not medically biased.

- ***The spell check is English – either British or American. In the interests of consistency, only one of these can be selected and is applied globally.***

1.2.9 Toolbar Icons

As shown on Figure 1 the toolbar icons at the top of the update screen can be used as a shortcut to commonly-used PV-Works (vet) functions. These can include:



Create a report from this case
Write a letter using data from this case
Approve the case for reporting
Create an Action Board task (see section 9)
Create narrative summary Access coding screen
Return to the Main Menu (current case is left open)

By holding the mouse over the icon, hover hint text will tell you its function.

The System Administrator can control the icons that you will actually see.

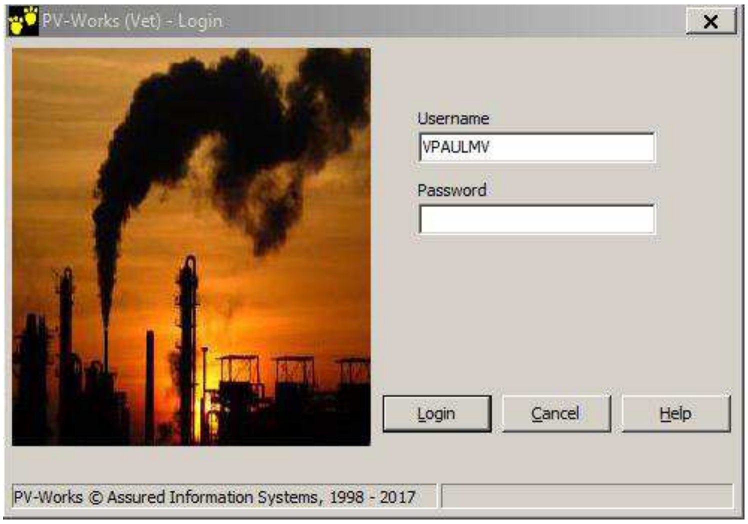
2 Starting PV Works

2.1 How to log on to PV-Works (Vet)

1. The PV-Works (vet) system will have a shortcut icon on your Windows desktop or in your Citrix Metaframe Menu system. Please ask your local Systems Administrator for details.

By double clicking this icon the PV-Works (vet) log-in screen is presented. See Figure 16 below.

Figure 16 - PV-Works (vet) Logon screen



3. Type in your **user name** - Usernames are not case sensitive and will always be displayed in lower case
4. Type in your **password -** Passwords are case sensitive. If the CAPS LOCK key is on a warning message will be given as this is a frequent cause of invalid entry.
5. Click **Login** or press the **Enter** key.
6. Upon successful verification of the user name and password, the user is logged on to PV-Works and the system displays the main screen.

✎ ***You have THREE attempts to log into the system. If the third attempt fails, your account will be locked out of the system until it is re-opened by the System Administrator.***

2.2 How to log out of PV-Works (vet)

PV-Works (vet) uses the Windows standards for exiting a system.

1. If you are updating a case (i.e. data entry screen) when attempting to log out of PV-Works then a message is displayed informing that all cases must be closed before exiting (see below).
2. ‘Cancel’ or ‘Save and Exit’ the case.
3. Exit PV-Works.
4. Confirm the logout when prompted.

Note that all cases must be closed before the user may exit the system. If cases are open at this time the following message will be shown:

NB It is possible to exit PV-Works with open cases by using the ‘Force Exit’ option.

3 PV-Works (vet) Main Screen

The PV-Works (vet) main screen is the core screen of PV-Works (vet) and is one of the primary methods of changing the current case and of carrying out a task.

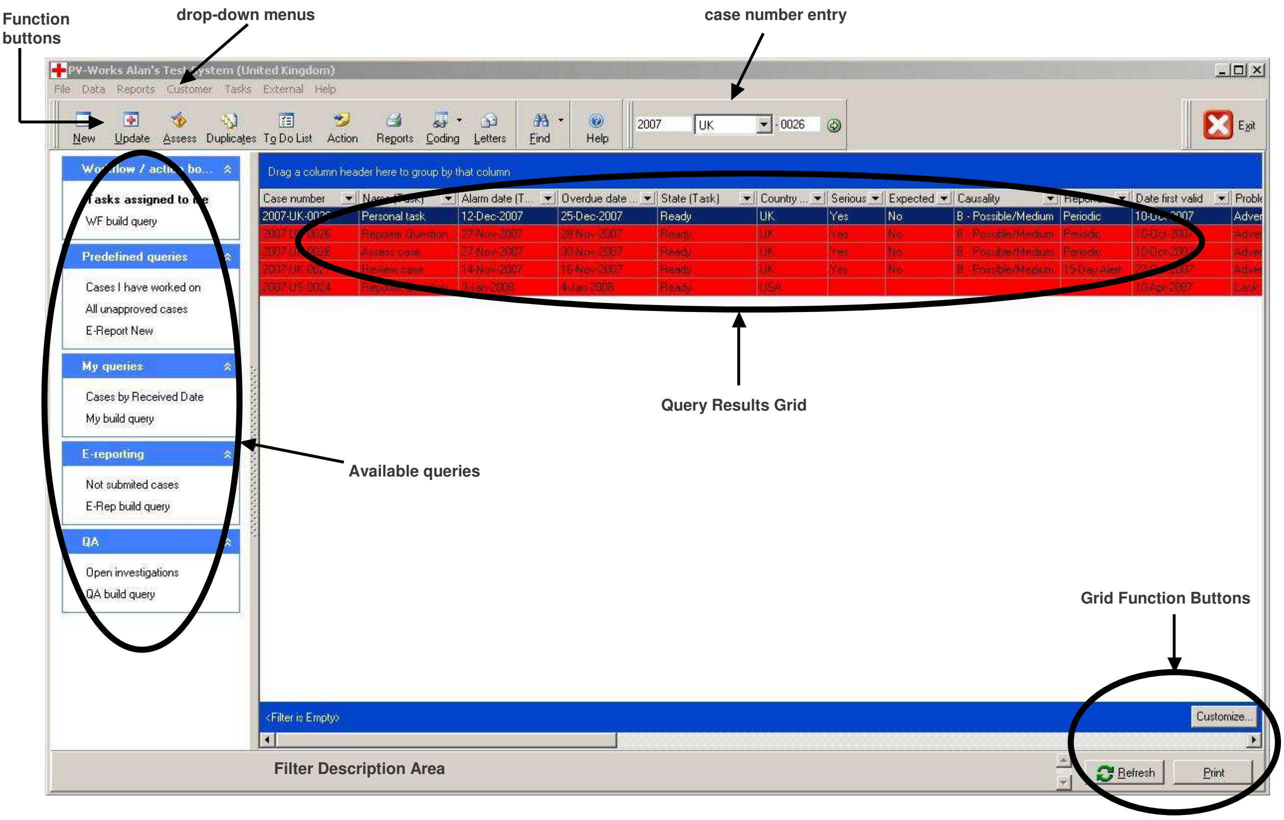
Using a main screen query grid to drive case access

1. The main screen grid (see Figure 17) offers a powerful query engine to users and will be extremely useful for reviewers and any user who queries the database.

   Key functions of this screen include:

   - Ability to define any number of queries (including workflow to-do list queries)
   - Queries may be executed and re-executed as required
   - Queries can be given parameter data at run-time, thus increasing their flexibility
   - Sort, group and filter the results
   - Ability for the user to define which columns of data are displayed, using a right click 'field chooser' to select columns

Figure 17 - Main Screen Grid

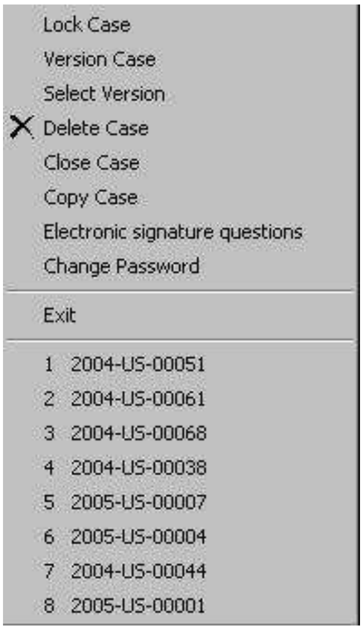


3.1 Drop Down Menu Options

The following menu options and sub-options are available via the drop-down menus at the top of the screen. The precise options available to the current user depend on the user's security rights, i.e. the user only sees those options to which the System Administrator has granted access.

Menu option Functions

File Lock



case ***or*** Unlock case

Creates a new version of a case

Select different version of a case

Deletes a selected case, once deleted this case cannot be viewed

Closes a case and the case can still be viewed.

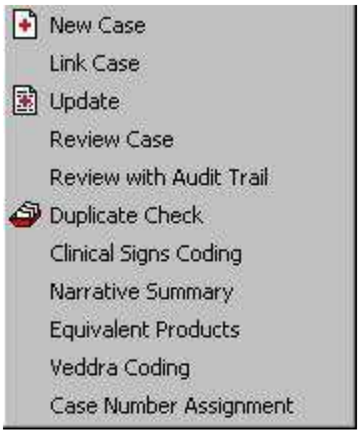
Change electronic signature password(s)

Change log-on password

Exit from PV-Works (vet)

Select one of the 'most recently used' cases

Data



Creates a new case

Links two or more cases together

Selects the case Data Entry screen

Reviews the case - no update allowed

As above - with the changed fields indicated in Red Performs the Duplicate Search function

Selects clinical signs coding for this case.

Summarise the narrative for this case

Define product names in other countries for this case

Code case against VeDDRA

View / edit case numbers associated with this case

Report

Print individual case reports (Regulatory & internal)

Multi- case print of individual reports

Approve a case for official submission

Multi-case report selection and submission

PSUR report selection and submission

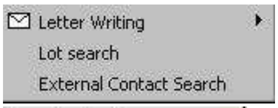
Record actual submission of reports

Undo a recorded submission of reports

Tasks

To Do List	Display 'to do' list
Case Actions	Display process for current case
Workload Manager	Workload management for the system
Create Ad Hoc Proc.	Creates an Ad Hoc process for this case
Review action board activites	Review progress with all outstanding action board tasks.

External



Letter writing – create and batch queue

Search cases for product lots

Search dictionary for contacts

Help

on-line help system

Toggles on/off the Main and Search toolbars

Information about the PV-Works (vet) system

4 Adverse Event Case Data Entry

4.1 Introduction

The PV-Works (vet) data entry and update functions are designed to:

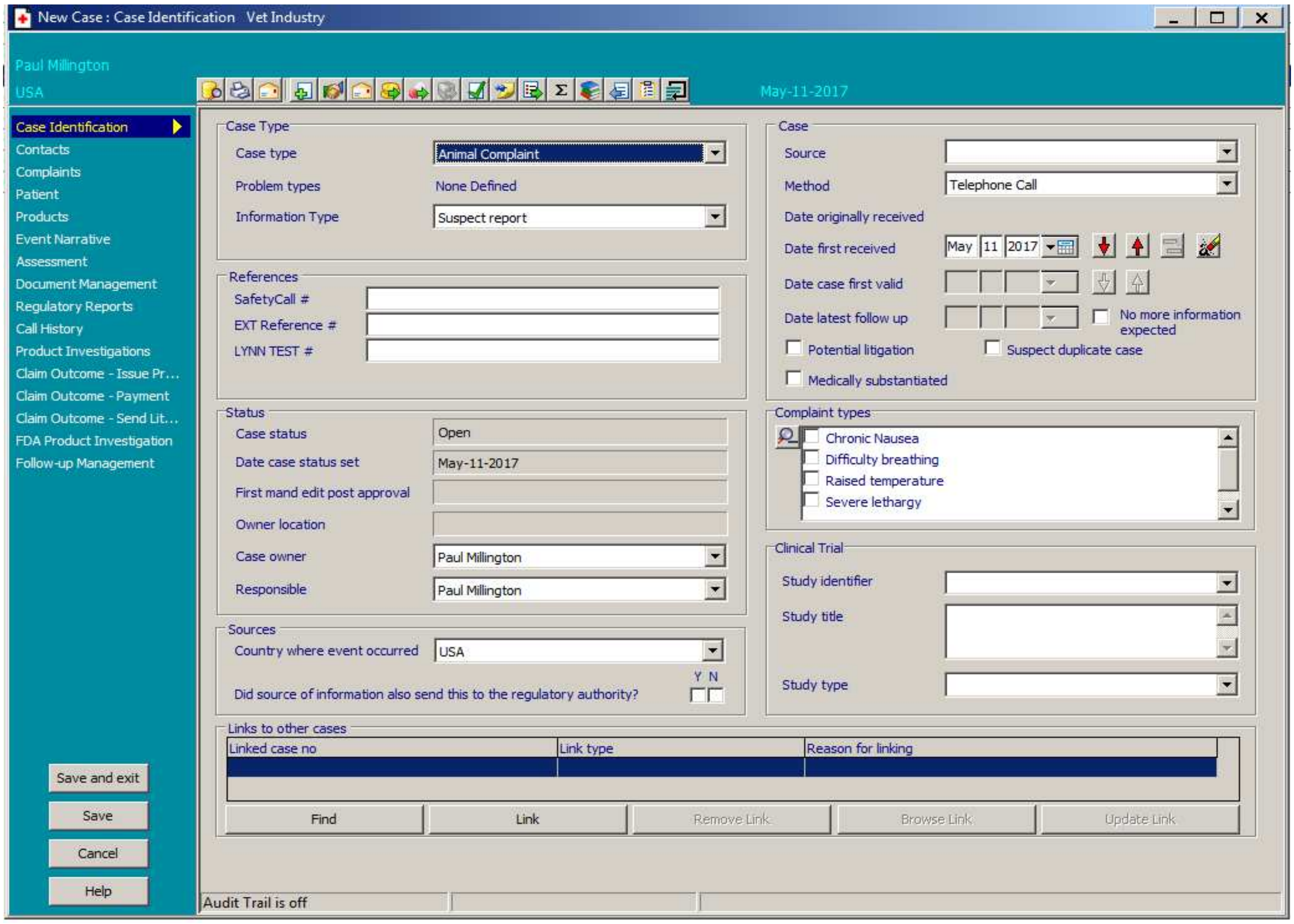
- provide easy-to-use screens that are intuitive in operation
- make extensive use of code lists to promote standardised data entry
- provide data validation at source so that correction can be made at the earliest opportunity

It is recognised that entry of case data can be a time consuming activity and one that may be interrupted by another task. PV-Works (vet) addresses this by registering the basic case information in a first step termed 'Initialising a Case'. This establishes the case in the database, giving it a system-generated case number and initiates a workflow process to control its progress.

4.2 Creating a New Case

In order to control the processing of an adverse event report, a case must be created in the PV-Works (vet) database. The 'New Case' option registers a new case into the database for the first time.

Figure 18 - New case screen



4.2.1 How to Create a New Case

From the **Data** Menu select **New Case** or by using the new case icon 

.

The system will present you with the 'new case' screen as shown in figure 18 above.

The Systems Administrator can configure the screens that are shown to you in the New Case step and their order of presentation.

3. The minimum information that must be entered in order to create a case is:

- Case Type
- Date Received
- Country where event occurred

Typically, of course, more data is entered.

4. Select **Save** 

to save your new case. The system will ask you to confirm the save.
5. Once saved the system will generate the case identification number and allow you to continue if necessary with entering the remaining case information.

If the Systems Administrator has only defined one workflow process for the whole system then this will be assigned to the case automatically. If more than one process template is available the user will select the appropriate one from a list.

4.3 Case number or identifier

When a new case is saved to the database it is assigned a case number by PV-Works (vet).

The number at the end identifies the revision number of the case.

The phrase a 'new case is saved' strictly means a 'new report', as it is possible that the information received at this stage does not comply with the strict VICH definition of a case – or it is not an adverse reaction at all, e.g. an enquiry.

The format of the case number is determined by a system option set by the System Administrator. It may be a simple numeric sequence number or a composite case identifier that includes elements such as year of receipt, country of origin, case type and some predetermined fixed text.

Every case number designed by the Systems Administrator must include a sequence number element. This is incremented by PV-Works (vet) automatically when a new case is saved and ensures uniqueness of case identifiers.

4.4 Case Number Display

PV-Works (vet) allows the user to change how the case number can be entered on the main screen. The number can be entered either as one whole number or by typing in the component parts.

- **Individual Boxes**

This allows the user to change a part of the case reference, the system uses drop down lists and scroll lists where appropriate. You can select this case by choosing  or by using the enter key.

- **Single Edit Box**

This allows the user to type in the case reference in one single edit box. Again you select the new case by using the enter key.

4.4.1 How to change the Case Number display

1. Using the mouse, hover over the case number area.
2. Select the Right Mouse button and a set of options will appear:

3. Highlight the option you require and then select using the Left Mouse button.
4. The system will then change the display to your selected option.

4.5 Assigning a workflow process

When a case is initialised a workflow template is assigned to it. The template controls the tasks that are required to evaluate distribute report and archive the case.

Once the workflow process has been assigned to the new case, PV-Works (vet) calculates the target dates for each task based upon the date of receipt of the report and the expected duration for each task. The first task (or tasks) is automatically ready to be carried out and will immediately appear in the 'to do' list of the appropriate users.

5 Data Entry: Actions for Complaints and Enquiries

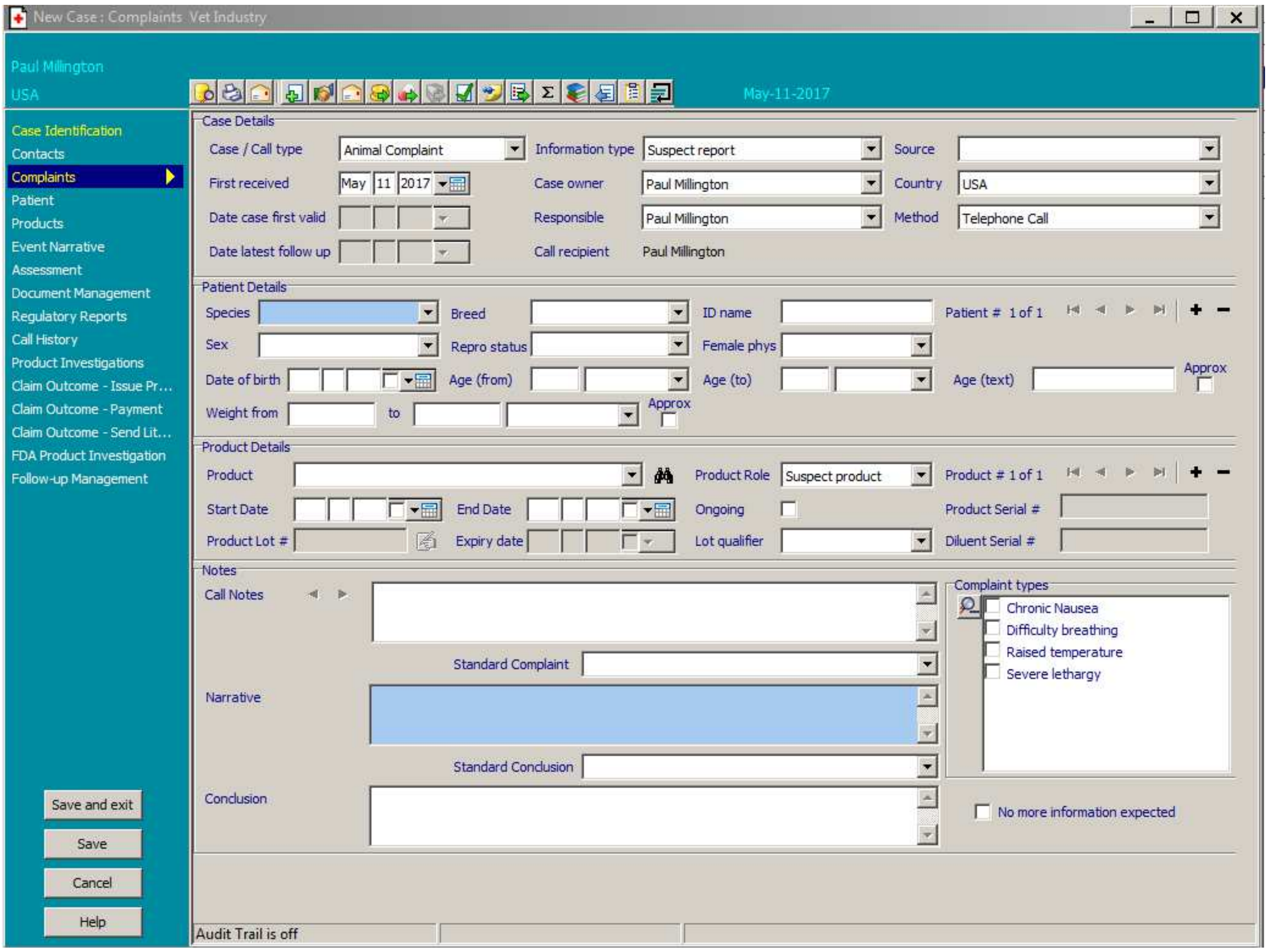
5.1 Introduction

Entry and processing of Complaints and Enquiries follows the same principles as Adverse Event cases (see section 6).

5.2 New Complaint / Enquiry

Most of the data that may be entered into the Complaint screen (Figure 19) is also present on other data entry screens. For example, product name in the product screen, species and breed in the patient screen. Entering or editing data in one screen is automatically reflected in the other.

Figure 19 Complaints Data Entry Screen



The Complaints screen is focused on case creation from information provided by a telephone caller. For simple calls it is possible to open and close the call from this one screen.

5.3 Handing Over Calls

During the call the Helpdesk staff may recognise that the caller needs to speak to a second tier support person. Both the telephone call and the complaint data that has been entered to the point of handover may be forwarded to the next support person.

The 'Handover Call' button  in the case toolbar will allow a user to hand the call over to any other user (by name) or to a group (e.g. support vets).

Figure 20: Handover Call Screen

5.4 Processing a Complaint

PV-Works (vet) offers four functions in response to a complaint or enquiry:

1. Authorise payment of a cheque or credit.

   Note that PV-Works (vet) does not write the cheque or amend your accounts system. It simply authorises the payment.

2. Create an order for distribution of complimentary product

3. Create a list of standard literature – internal documents and/or scientific papers – that answer the question.

   ✐ ***It is possible to send these documents directly to the complainant / enquirer via email or fax.***

4. Issue a laboratory box in order to collect a field sample.

For each of these a covering letter may be generated directly from the system, merging case data with standard text.

6 Coding

Within PV-Works (vet) it is possible to code adverse event terms against a company-defined dictionary and/or against VeDDRA. Many companies are now standardising on VeDDRA as their only coding dictionary, partly due to its acceptance by EMEA and FDA.

In order to improve the data quality for analysis the adverse event narratives may be coded. This is a separate function with its own security rights and access. The user selects one or more clinical signs terms from a look up list defined by the System Administrator.

6.1 How to start Coding

1. You can access Coding

- From the main menu select **Data** and **Clinical Signs Coding** or **Data** and **VeDDRA Coding** *or*
- Select the Coding icon from the main screen

And then select the appropriate coding dictionary from the sub-menu

or

- Select the View/Edit Coding icon from the Event Narrative.

This will take the user to VeDDRA coding only

6.2 VeDDRA Coding

1. The VeDDRA Coding Summary screen will appear. See Figure 21. The event narrative and its VeDDRA codes are displayed.

   The user may enter text to search the VeDDRA dictionary in the 'Search text' box.

   ✐ ***The text used for searching does not need to be a complete word. The search tool can add 'wild characters' to both sides of the search word.***

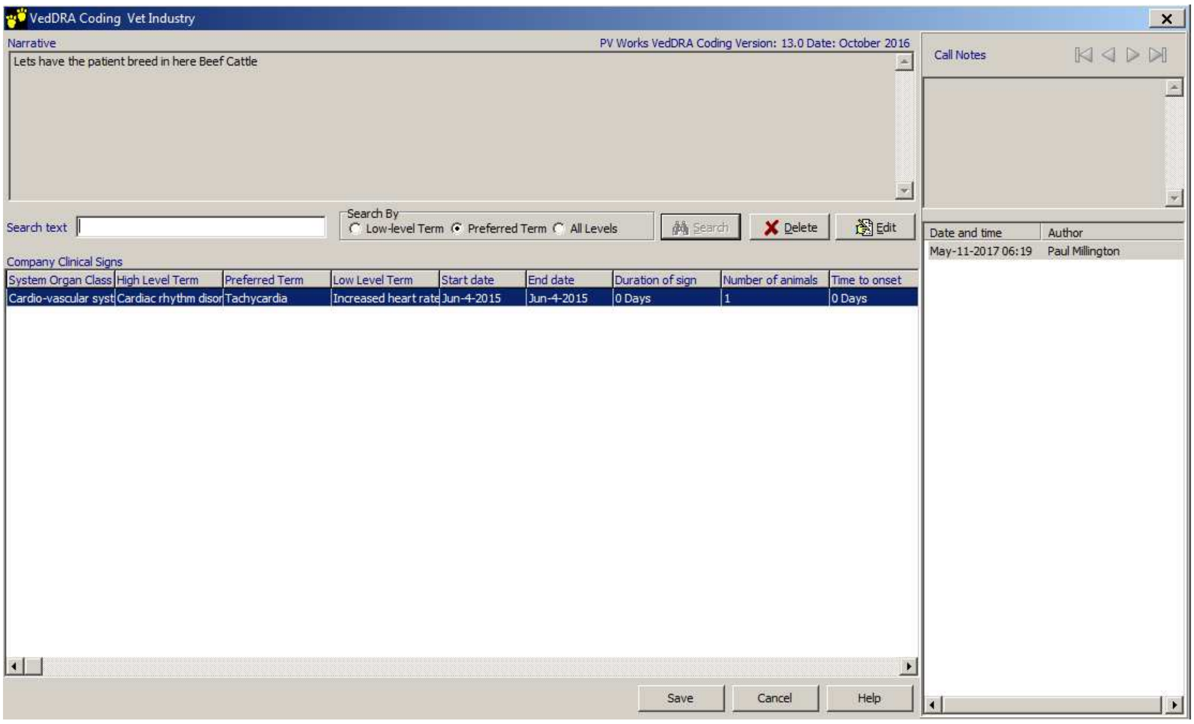
   ✐ ***Text can by 'copied' from the case narrative and 'pasted' into the search text box using ctrl-c and ctrl-v.***

   The user has three options to determine how the search text is applied to the dictionary:

   - Low-level term search
   - Preferred term search
   - All levels search

   One of these will be defaulted but the user may select one of the other options by clicking the appropriate radio button.

Figure 21: VeDDRA Coding Summary Screen



2. Low Level and Preferred Term searches are similar in operation.

- Select the Low level or preferred term option and click the Search button on the VeDDRA Coding Summary screen. This searches the VeDDRA dictionary for the closest matching term or terms in the LLT or PT VeDDRA lists and displays them on the screen in Figure 22.

PV-Works applies a hierarchy of search methodologies.

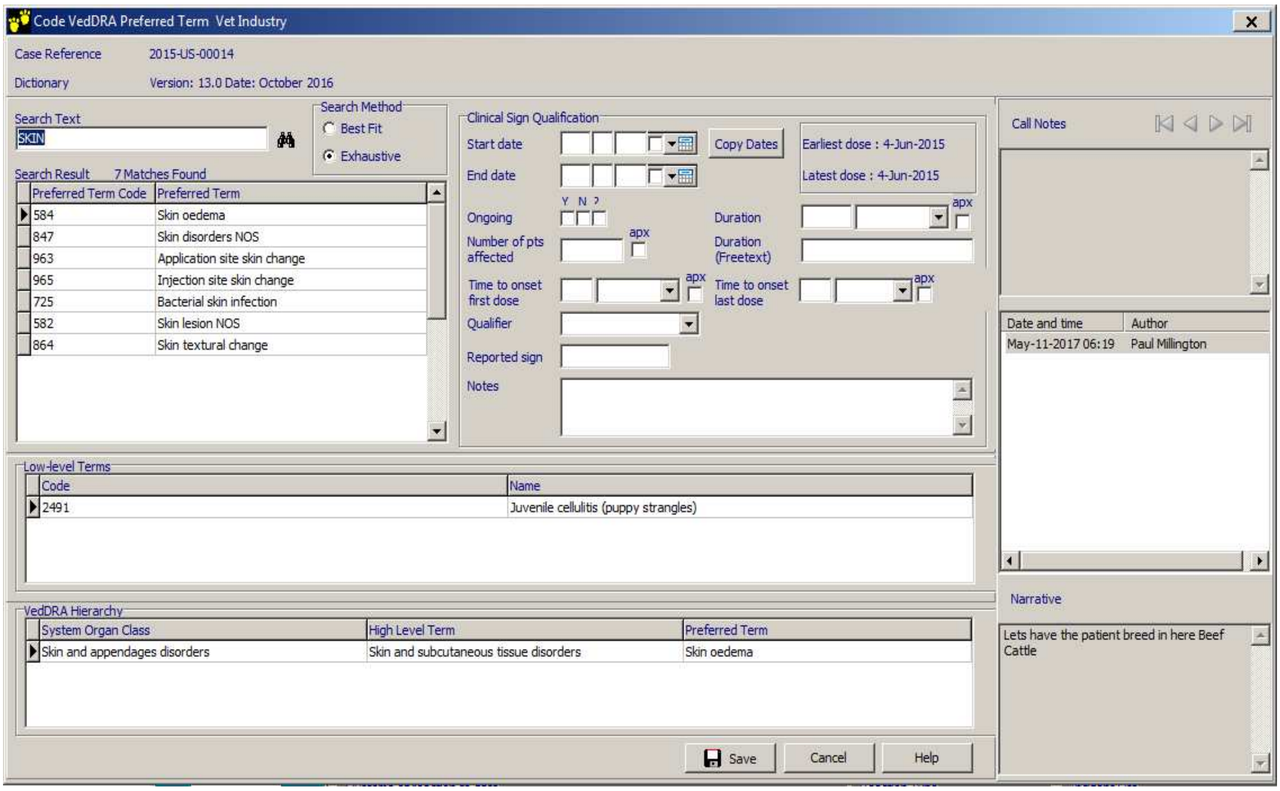
If an exact match between the search term and VeDDRA is made, then this term is displayed with no others.

If no exact match is found, then all terms that CONTAIN the search text are displayed. This is the format seen in Figure 22.

Finally, if no terms have been found, the system searches for terms that 'sound like' the search term.

The search engine is not medically intelligent and can make some odd proposals – particularly if it uses the 'sounds like' option.

Figure 22: VeDDRA Preferred Term Search



- The search text can be edited and the dictionary can be re-searched. This replaces the currently displayed terms 
    - If one of the terms displayed is the required one, highlight it by clicking the left mouse button at any point in the results grid.

In the example in Figure 22, “renal disorder NOS” has been selected and is shown with a blue highlight.

- Optionally the user may add clinical sign qualification data such as the start / end date of the sign.

✎ ***The time to onset of this sign to the earliest and latest date of administration is calculated automatically***

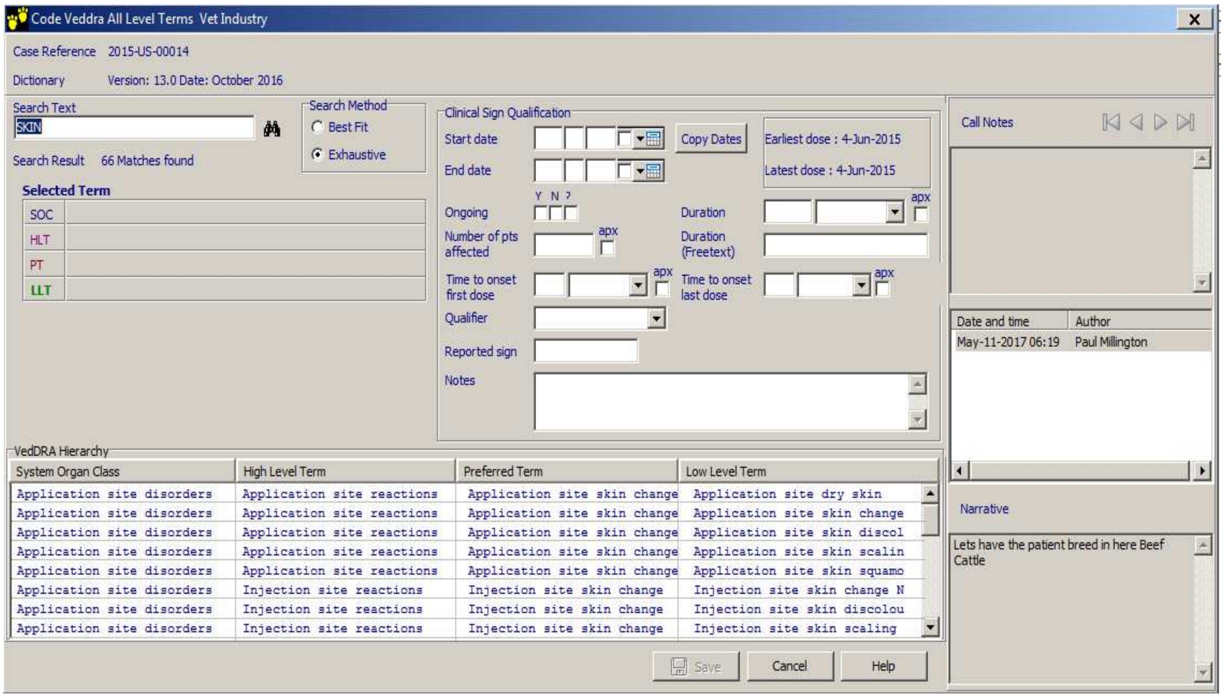
✎ ***Start and end dates may be copied from the ‘previous’ clinical sign using the ‘copy dates’ button. This is useful when several signs are entered all for the same date range.***

- ❑ The Clinical Sign and all qualification data are saved back to the summary screen in Figure 21 using the 'save button'

3. All Levels search.

- ❑ Select the All Levels option and click the Search button on the VeDDRA Coding Summary screen. This searches the VeDDRA dictionary for the closest matching term or terms in all four VeDDRA levels (SOC, HLT, PT and LLT) and displays them on the screen in Figure 23

Figure 23: VeDDRA Coding Screen - all levels



- ❑ The search text can be edited and the dictionary can be re-searched. This replaces the currently displayed terms

- ❑ If one of the terms displayed is the required one, highlight it by clicking the left mouse button at any point in the results grid.

In the example in Figure 23, “renal disorder NOS” has been selected and is shown with a blue highlight.

In order to select a clinical sign, the row in the grid must show an entry in all four levels, ie including low level term.

Where a match has been found at a level above the Low Level, a + sign appears. Click this button twice to expand the list:

Renal and urinary disorders	+ Renal disorders		

expands with ‘double-click’ to:

Renal and urinary disorders	+ Renal disorders		
		+ Anuria	
		+ Nephritis	
		+ Nephropathy	
		+ Oliguria	
		+ Polyuria	
		+ Renal disorder NOS	
		+ Renal failure	
		+ Renal insufficiency	
		+ Renal vascular disorder	

and again to

Renal and urinary disorders	+ Renal disorders		
		+ Anuria	
		+ Nephritis	
		+ Nephropathy	
		+ Oliguria	
		+ Polyuria	
		+ Renal disorder NOS	
		+ Renal failure	
			Acute renal failure
			Chronic renal failure
			Renal failure
		+ Renal insufficiency	
		+ Renal vascular disorder	

now the term 'Chronic renal failure’ may be selected.

- Optionally the user may add clinical sign qualification data such as the start / end date of the sign.

The time to onset of this sign to the earliest and latest date of administration is calculated automatically

Start and end dates may be copied from the ‘previous’ clinical sign using the ‘copy dates’ button. This is useful when several signs are entered all for the same date range.

- The Clinical Sign and all qualification data are saved back to the summary screen in Figure 21 using the ‘Save’ button.

.

4. Saving new and edited VeDDRA codes to the database

- The Clinical Sign and all qualification data must be saved from the summary screen in Figure 21 to the database using the ‘Save’ button.

Simply ‘displaying’ the new codes on this summary screen and then clicking ‘cancel’ will not result in the codes being saved. It actually ignores all of your new data and edits

7 Data Entry and Actions for Product Investigations

7.1 Introduction

Entry and processing of Product Investigations follows the same principles as Adverse Event cases. Product Investigations are typically set running by a product support specialist and passed to QA.

An investigation can be run on any product lot or diluent or serial.

A case can generate up to 26 investigations … but two or three is a practical maximum!

An investigation may be retained by the product support specialist where the manufacturing QA group is not a PV-Works user

An investigation may be created for cases that are not categorised as 'product defects' and not all 'product defects' need to be investigated

The QA group can review cases and initiate an investigation if this has been 'missed' by the product support team

This section describes the most common usage of the product investigations module

The Product Investigations module is tightly integrated with the workflow and action board modules. See section 9 (Data Review) for details.

7.2 Creating an Investigation

1. From the product screen

- Ensure that 

the field has data. If not type a value. While it is possible to create an investigation on cases without lot numbers, the actual investigation is not practical

- Click the 

to make a request

  ✎ ***You can classify a Product Defect via the binoculars button*** 

- Create an Action Board task to ask a responsible user to obtain a sample (optional)

7.3 Sending an Investigation to QA

1. From the product investigations screen, the user can send an investigation to QA. Choosing the correct workflow process determines the receiving QA group.

- Click the 'Send to QA' button 

- Select the correct workflow process

  ✎ ***Note that it is possible to select a second workflow for products with multiple manufacturers (typically biological products)***

- Click the 'Create / Save' button to create the workflow process and to save any other data on the screen 

✎ ***Note that the current workflow status of the investigation is displayed on the Product Investigation screen so that the 'sender' is aware of this status at all times***

7.4 Running an Investigation

1. The QA user will typically access all active investigations from the workflow 'to do' list. The basic steps are:

- Review the investigation request (on the Case Details screen) and then categorise it (on the Case Identification screen).

  ✎ ***The case identification screen displays the workflow process and can be used to mark tasks as complete***

- Add laboratory tests. These can be added singly or as a group using the  button.

Note it is possible to include tests from previous investigations where these occur for the same product and batch number

- Approve the laboratory tests. (optional and set on/off by the System Administrator)

- Create a laboratory request form

- Enter the laboratory test results. Optional fields include the technician’s name, a comment on the adherence to specification and a cross-reference to the laboratory note book

- Approve lab test results (optional and set on/off by the System Administrator)

- Write conclusion

- Approve conclusion

Note that the user who writes the conclusion cannot approve it

The approval of the conclusion is the signal that the investigation is complete. This returns the conclusion to the Technical Support team. Only the conclusion narrative is visible to these users.

7.5 Reviewing the results of the Investigation

1. When the investigation is complete, i.e. the concluding summary has been approved, this statement is made visible to the Technical Support team and all other users who are granted access to the Product Investigation screen

2. At all times the QA concluding narrative is ‘read-only’

3. The Technical Support team may copy and paste all or part of this narrative into the Event Narrative so that it may be reported to a regulatory authority. Once copied into

the event narrative the text may be changed, but any changes are NOT reflected into the QA concluding statement.

8 Function Keys

You can navigate around PV-Works (vet) using keyboard functions. The table below explains the keys enabled:

8.1 Menu Options

To	Press
File Menu	ALT and F
Data Menu	ALT and D
Reports Menu	ALT and R
Task/workflow Menu	ALT and T
External Menu	ALT and E
Help Menu	ALT and M

8.2 Moving between data entry screens and multiple records

To	Press
Next data entry screen	PAGE DOWN
Next record card (right)	RIGHT ARROW
Previous data entry screen	PAGE UP
Previous record card (left)	LEFT ARROW
Last record	CTRL and DOWN ARROW
First Record	CTRL and UP ARROW
Next Record	CTRL and LEFT ARROW
Previous Record	CTRL and RIGHT ARROW

8.3 Moving between fields and around the screen

To	Press
Backwards between fields	SHIFT and TAB
Display a drop down list	F4
Down a drop down list	DOWN ARROW
Down a scroll box	DOWN ARROW
Down radio buttons	DOWN ARROW
Forwards between fields	TAB
Up a drop down list	UP ARROW
Up a scroll box	UP ARROW
Up radio buttons	UP ARROW

8.4 Updating records

To	Press
Add a new record	CTRL and +
Cancel changes	ALT and C
Clear a check box	SPACE BAR
Delete a record	CTRL and -
Save a record	ALT and S
Save and Exit	ALT and X
Select a check box	SPACE BAR
Undo typing in a text field	Shift F10

8.5 Editing Text

To	Press
Copy text	Highlight text and SHIFT F10 and C
Cut text	Highlight text and SHIFT F10 and T
Delete Text	Highlight text and SHIFT F10 and D
Highlight Text one word at a time	CTRL and SHIFT and ARROW KEY
Highlight Text one word at a time	SHIFT and ARROW KEY
Select all text	SHIFT F10 and A
Paste Text	Copy or Cut text and SHIFT F10 and P
Undo Typing or last action	SHIFT F10 and U

8.6 Help Keys & Exit

Help	ALT and H
Exit from current window	ALT and F4
Exit from PV-Works (vet)	ALT and F4

9 Data Review

The Data Review function is similar in principle to Data Entry / Update with the important difference that no data may be amended or entered. All data is displayed in dark grey text to indicate clearly that it is in a read-only state.

The order of the screens displayed in a Data Review function can be controlled by the Systems Administrator and may differ from those available in Data Entry if required.

9.1 How to Review your case

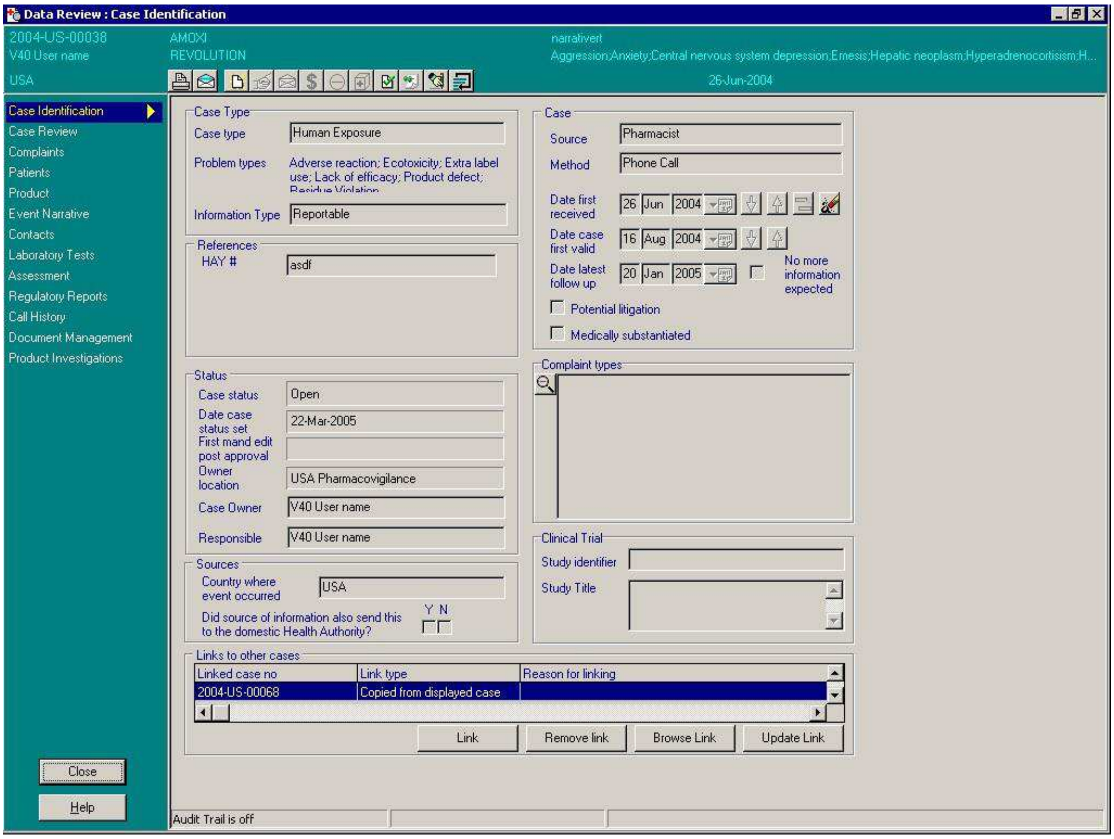
1. From the main screen select **Data** and the **Review** options.

All of the data entry screens are available to view, but all of the information is greyed out.

See

2. Figure 24 below.
3. The only options available are:
   - Close - Exit from Data Review mode
   - Help - Access the online help.

Figure 24 - Data Review Mode



10 Workflow Processes

PV-Works (vet) includes two types of workflow function:

a) a comprehensive workflow module called Pipeline that can link together tasks into a complete chain or process with task assignment and target time calculation. This is ideal for control over the main business flow, e.g. 15-day reporting. For more information please refer to the Pipeline Implementation and User Guide

b) a 'single task' function called an Action Board that allows a user to set a single task for another user. With this function there is no automated follow up task when the single task is complete

Both functions have value. Assured sees the Action Board as a sub-process function for use with one-off ad hoc tasks.

PV-Works (vet) includes 3 levels of workflow access:

- Case level,
- Manager level
- Administrator level.

The access is controlled through your User ID and can be amended by the system administrator. This guide gives a brief overview of the Case level and Manager level options. The Administrator level refers to the workflow design and publishing functionality available via the separate PV-Admin program.

10.1 Case Level Workflow

At case level, the user can:

❑ View and action Workflow for the pools the user is attached to	***PV-Works (vet) Main Menu*** ***Tasks assigned to me query results / To-do list*** Button
❑ Attach additional Workflow processes to a case	***Tasks - Ad Hoc Processes***
❑ Review the tasks that have been performed on a case and those that are 'ready'	***Tasks – Case Actions***

10.2 The tasks assigned to me query / the to-do list

The tasks assigned to me / to-do list shows tasks in three colours and two styles. The colours are:

- Red – the task is late. It should have been completed by this time in an ideal process flow
- Blue – the task should have been started by this time but is not yet due to be completed
- White – the task is assigned to you but may not need to be started yet, i.e. it is ahead of schedule

(Please note that this colour scheme can be amended by the system administrator)

The styles are (to-do list only):

- Heavy red/blue background with white writing – case is serious (or had not been assessed yet)
- Red/blue text on a white background – case is non-serious

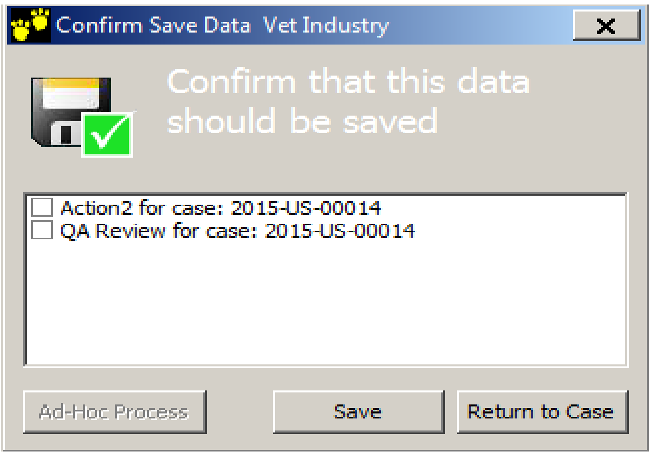
✐ ***All task target dates are calculated with reference to a time line calculated from the date the case is received. The fact that a task that is assigned to you is late does not always mean that you caused it to be late. The delay could have been caused earlier in the process and your task was only assigned to you after its ideal completion date.***

To execute a task, double click the row of the 'to do' list. Normally this will show you a PV-Works screen with your case data loaded. Commonly this is the update screen.

10.3 Completing Tasks on Save

On return from the update function PV-Works will allow you to mark the task as 'complete'. The system never assumes you have finished just because you have saved the data. The standard 'save and exit' screen shown in Figure 2 is amended as Figure 25:

Figure 25: Save and Exit with Workflow Completion



To complete a task 'check' the box to the left of the description and then click 'Save'.

You can complete are many tasks as you wish simultaneously by clicking multiple boxes.

Only tasks allocated to you are available for completion

10.4 Manager Level

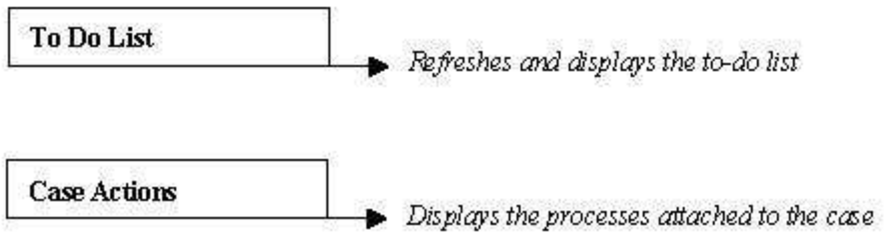
In addition to reviewing the current workload of teams and individuals, the Workload Manager can:

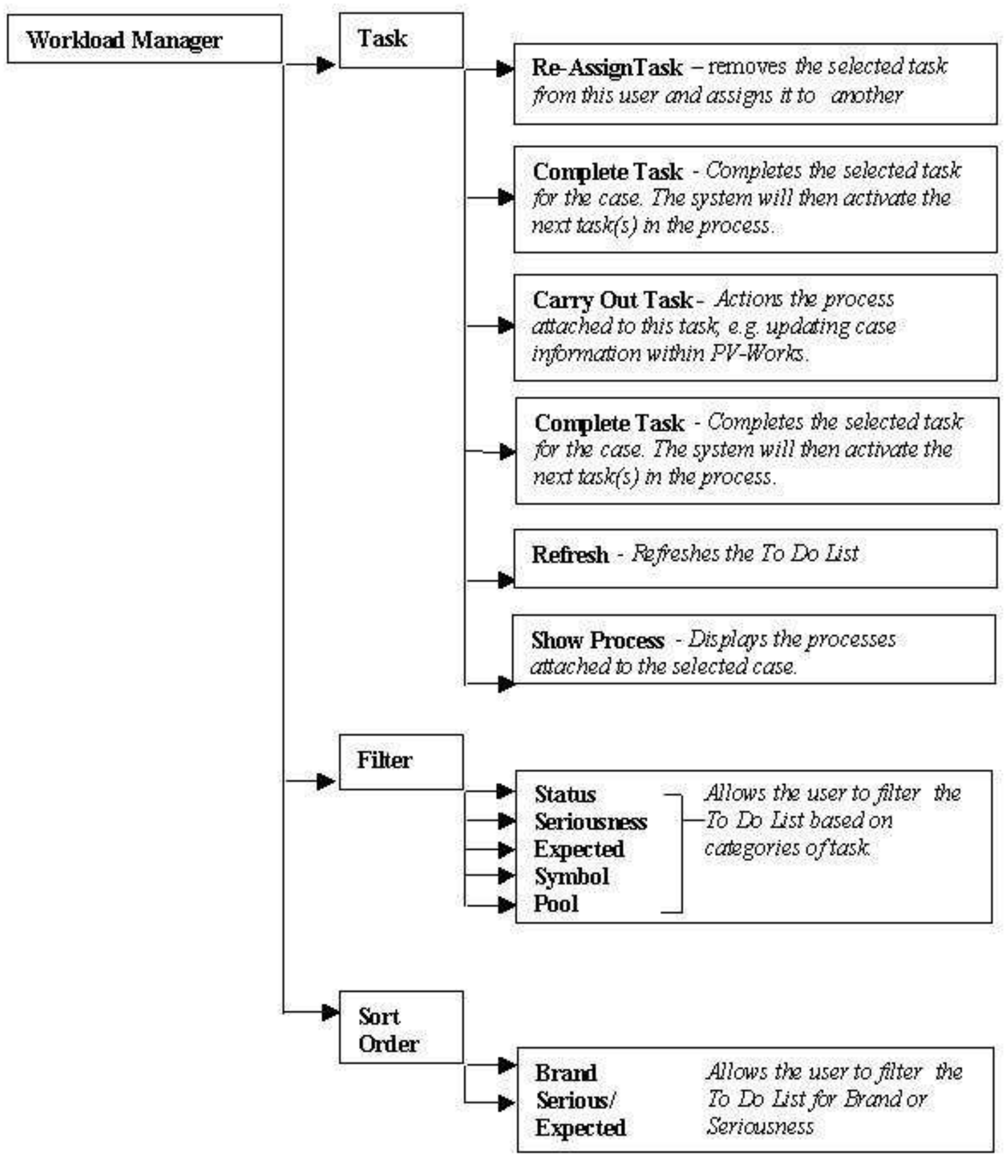
- Re-allocate acquired tasks to other users
- Return the task to the general pool of users
- Cancel the whole process

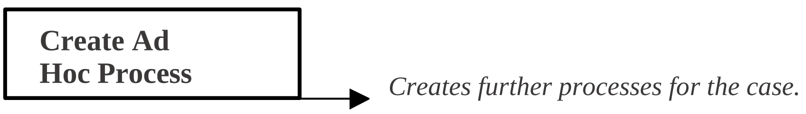
Tasks - Workload Manager

The System Administrator will configure the system to restrict the pools that each workflow manager may view

10.5 Workflow Menu Options




Workload Manager
Task
Re-AssignTask – removes the selected task from this user and assigns it to another
Complete Task - Completes the selected task for the case. The system will then activate the next task(s) in the process.
Carry Out Task - Actions the process attached to this task, e.g. updating case information within PV-Works.
Complete Task - Completes the selected task for the case. The system will then activate the next task(s) in the process.
Refresh - Refreshes the To Do List
Show Process - Displays the processes attached to the selected case.
Filter
Status
Seriousness
Expected
Symbol
Pool
Allows the user to filter the To Do List based on categories of task.
Sort Order
Brand
Serious/ Expected
Allows the user to filter the To Do List for Brand or Seriousness


Create Ad Hoc Process
Creates further processes for the case.

10.6 Action Board Tasks

10.6.1 Creating an Action Board Task

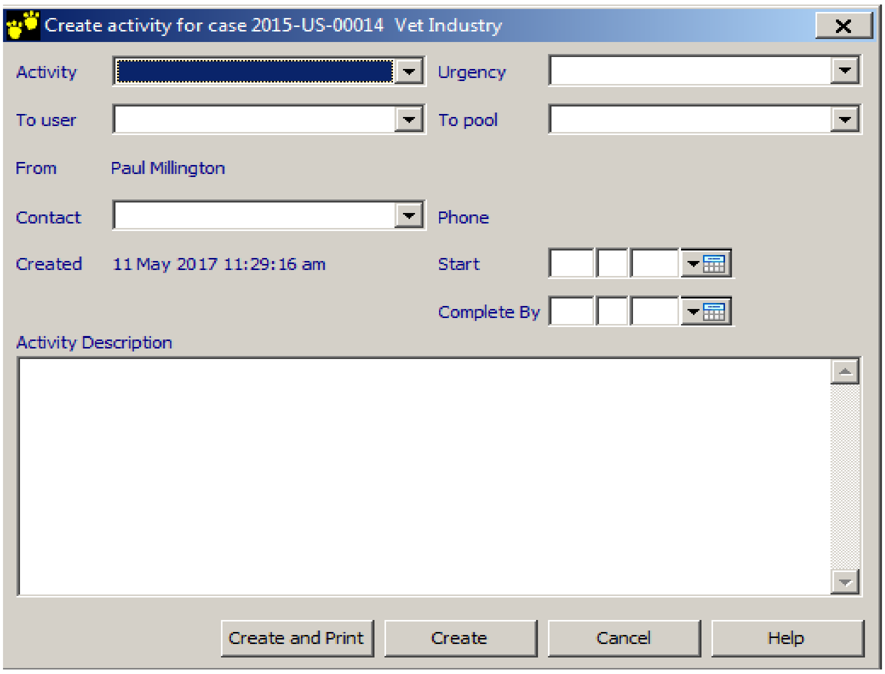
An Action Board task may be created from:

- The toolbar icon on the Main Menu; 

- The 'Action board' icon on the case toolbar 

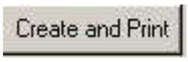
Clicking either of these icons will display the 'Create activity' screen shown in Figure 26.

Figure 26: Create Action Board task



By default, the user names in the 'to' drop down list are the names of PV-Works users in the same location as the message author. You send a message to PV-Works users in different locations by right clicking the mouse button and selecting 'all contacts'. This will place a global list of users into the drop down list.

✐ ***The user can send a task to themselves, ie to act as a reminder to do something. Eg call back to customer in a week to see how the animal is recovering***



- To create the Action Board Task, click either 'Create' or 'Create and Print'. The difference is that one button provides a paper copy of the action board task

10.7 Executing an Action Board Task

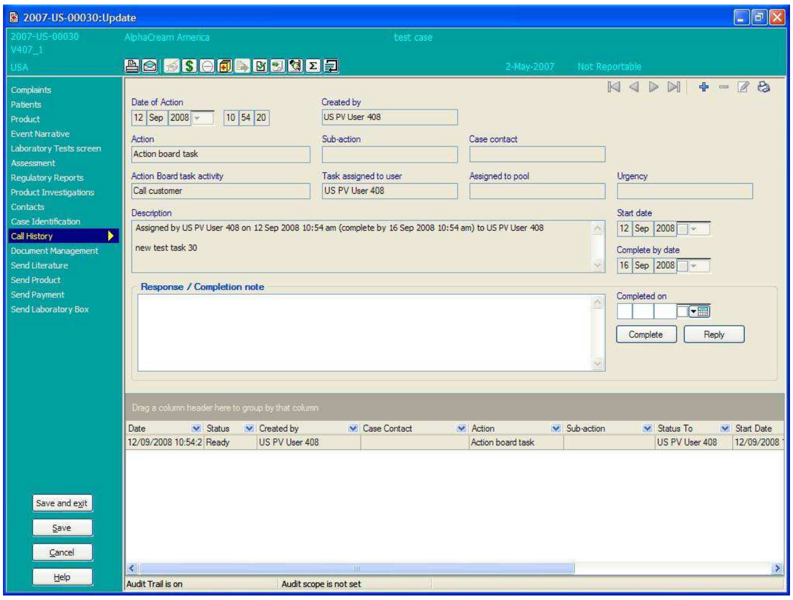
Action Board tasks that have been assigned to you to perform will appear in your 'to do' list. They can be executed simply by double-clicking the row of the 'to do' list.

✐ ***In appearance they look almost identical to those from workflow processes. The key is the colour of the icon on the left hand side. For Action Board tasks it is white as in Figure 27. For workflow tasks it is yellow.***

Figure 27: Action Board Tasks in the To Do list

When a task is executed then the task is opened on the Call History Screen within the case update container. This shows the task details that need to be performed as shown in Figure 28.

Figure 28: Execute Action Board Task



Execution of this task can take a number of different directions:

- Add some comments to the task – these will be retained when the case is saved, but the task will not be removed from the user's to-do list

- Complete the task now

To do this you must enter a completion date

✎ ***The 'today' button is a useful method of entering today's date with a single click***

A completion note can be added, but this is optional

- Reply … this sends another Action Board task to the person  who sent the original to you.

✎ ***Reply does not delete the task from your list. You can only do this by 'completing' it***

10.8 Managing Action Board Tasks

PV-Works (vet) provides a function where a user can review the tasks that they have assigned to other users to see if these have been completed.

You can view this list from the main screen by:

Selecting ***Tasks* | *Review Action Board Activities***

✐ ***The upper window shows tasks that you have assigned that are not complete*** ✐ ***The lower window shows tasks that you have assigned that are complete***

For tasks that are not complete, you can

- Delete the task
- Edit the description of the task
- Re-assign the task to another user

For tasks that are complete, you can

- Adjust the period (in days) for the display of completed tasks – based on completion date

11 Reports

PV-Works (vet) contains a number of regulatory and internal reports for both single and multiple cases. How to select a report from the main screen

You can run a report from the main screen by:

1. Selecting the Reports icon from the main screen 

2. The Select report screen will be displayed, see Figure 29 below.
3. Highlight the report name you wish to run and select 

Run.

Or by:

4. Selecting the Reports menu from the main screen
5. Then choose ‘Select Report’.
6. The Select report screen will be displayed, see Figure 29 below.
7. Highlight the report name you wish to run and select 

Run.

How to select a report from within a case.

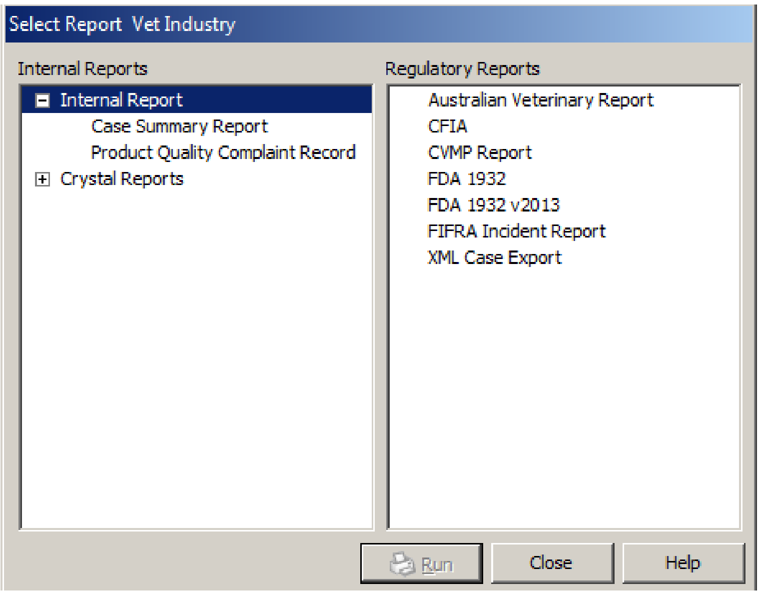
You can run a report from the Data Entry/Update screen by:

1. Select the Reports Icon from the top left hand of the  screen

2. The Select report screen will be displayed, see Figure 29 below.
3. Highlight the report name you wish to run and select 

Run.

Figure 29 - Select Report Options



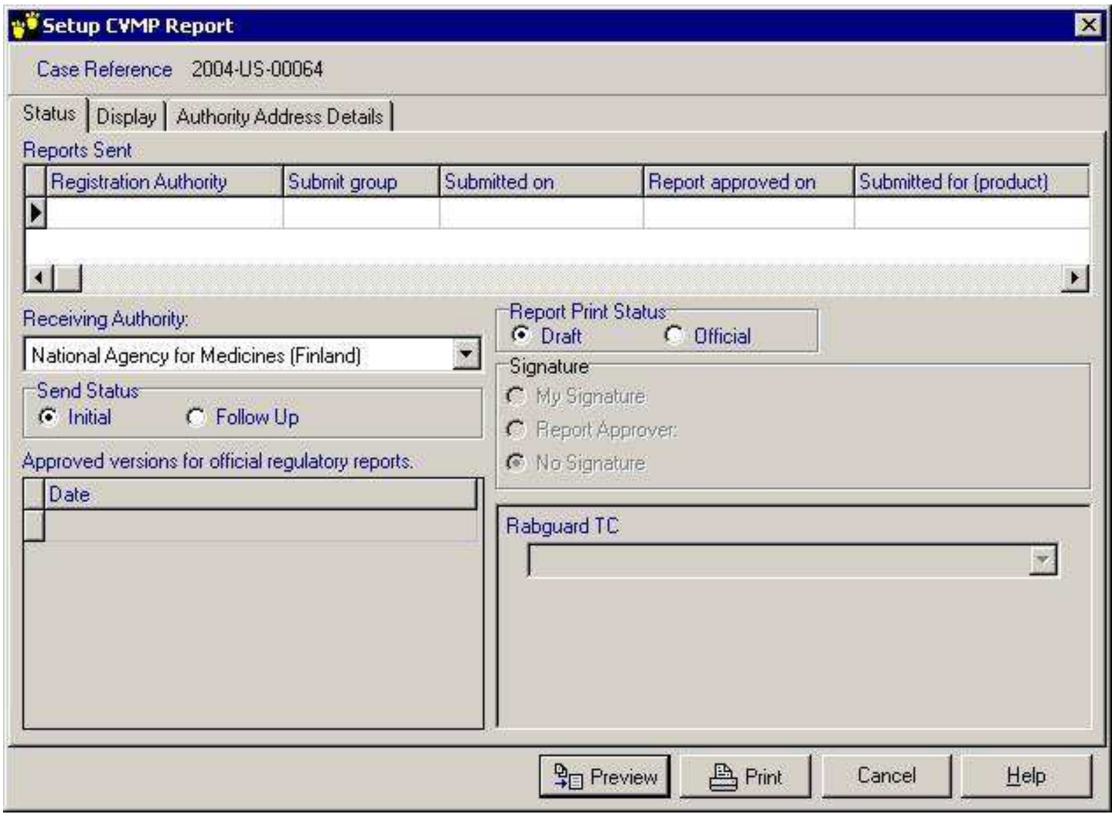
Note: The System Administrator may add any number of Crystal Reports to this screen. These may be written either by Assured or your development group. Crystal Reports appear in the left hand side window in an 'explorer-style' tree. (Click + to expand and – to delete)

Crystal Reports may be grouped into categories with a title set by the System Administrator and each has its own security setting. As a result the display may differ from that shown in Figure 29

11.1 Single Case Reports

Single case reports require the user to select various options before the report can be produced. The CVMP Report is shown as an example. See Figure 30 and Figure 31 below.

Figure 30 - CVMP Report Options



11.1.1 How to use the Status Report Options

For each report you can select the authority the report is going to, the report status and which product registration you are reporting against.

- Competent Authority — Select from the drop down list the authority required.

Note PV-Works (vet) can be configured to warn you if the selected agency does not accept the report type selected, eg FDA and a CVMP report; FDA and a biological product.

- Send Status — This is the status of the report.
  Select either Initial or Follow-up

- Report Print Status — This is the report printed copy status.
  Select either Draft or Official

- Signature — Official reports may include a graphical
  image of the responsible person's signature.

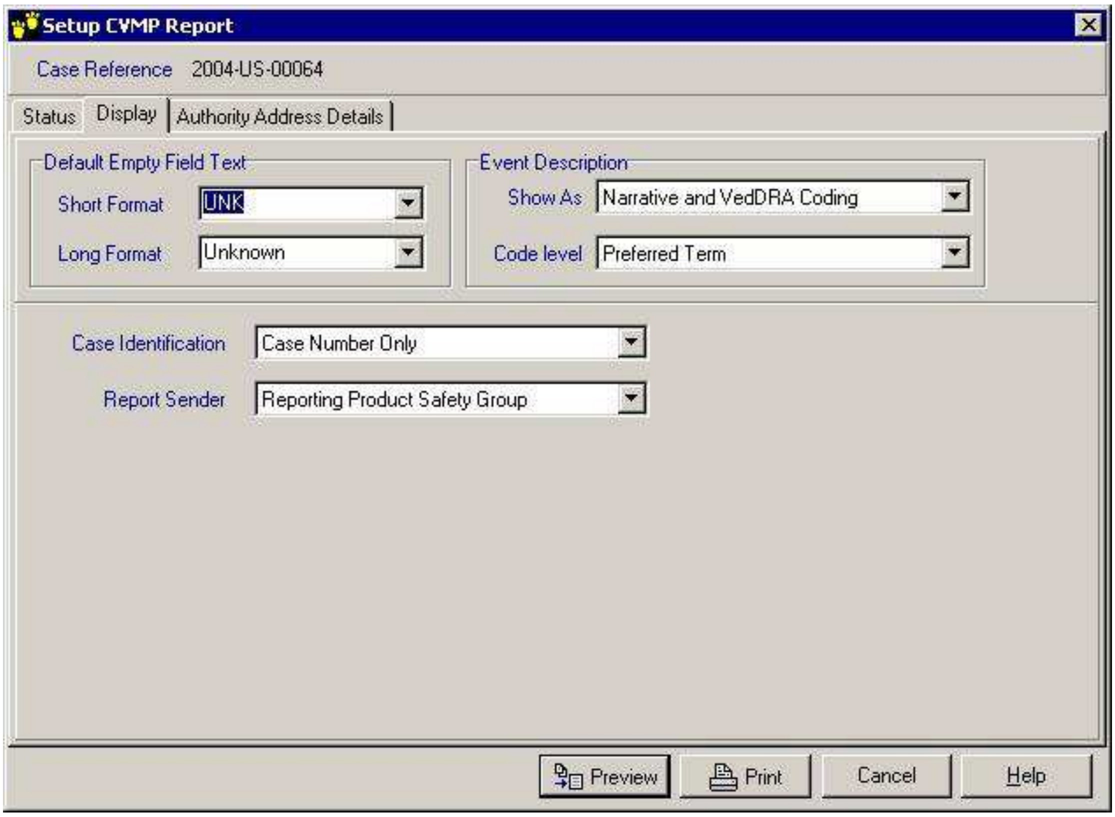
NOTE User signature images that are stored in the PV-Works database are encrypted for security reasons.

- Product Registration — This selects the product registration reported against.

  If there is only one product registration for the reported authority, this will be defaulted onto the screen.

  If there is more than product registered, select the product registration required from the drop down list.

Figure 31 - Report Display Options



11.1.2 How to use Report Display Options

For each report you can select how the report displays empty fields, event description, case identification and report sender.

- Empty Fields Selects the format of null fields on the report. Select either - Short Format :UNK or Blank, Long Format: UNKNOWN or Blank

- Event Description Selects the format for event descriptions

Selects either - Narrative Only or Narrative and Clinical Signs or just clinical signs

- Case Identification Selects the format for Case Identification
  Select either - Case Number Only or Case Number and another reference number eg Health Authority number, legacy system number

- Report Sender Selects the information for the Report Sender Select either Market Authorisation Holder or Manufacturer
  or Reporting Safety Group

11.1.3 How to generate the report

Once you have completed your status and display options you have the following options:

- **Preview** Previews the report on screen for printing or distribution electronically
- **Print** To print the report to paper
- **Cancel** To cancel generation of the report
- **Help** To access the on-line help

These options are described in detail below.

11.2 Print and Print Preview Options

11.2.1 How to Preview a report

PV-Works (vet) allows the user to preview any report before printing or distributing the report.

1. Select the ‘select report option. To display the report setup screen.

2. Select the Preview Report option. The preview report screen will be displayed (see Figure 32).

3. From here you have various options within print preview:

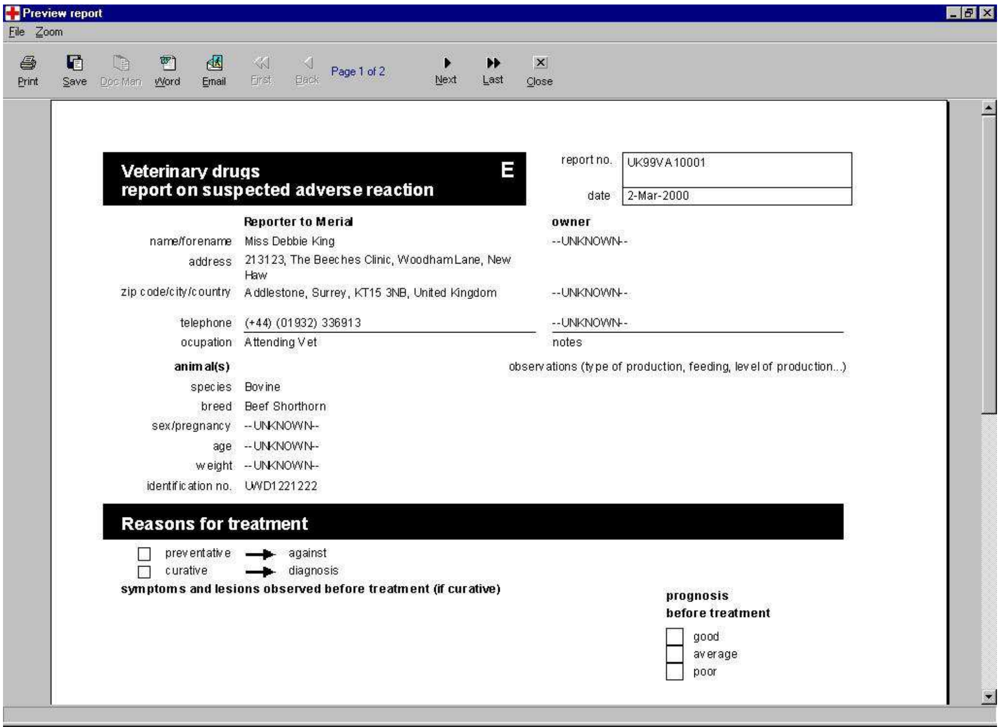
- **View** different pages using the First, Back, Next and Last buttons

- **Zoom** to make the report larger or smaller. You can also zoom in and out using the left and right mouse buttons respectively

- **Print, Save, save to Document Management, save to Word and send a report via email.**

5. **Exit** from Print preview by selecting the Close button

Figure 32 - Print Preview Screen



11.2.2 How to Print a Report

1. You can print a report directly from the report selection or via the print preview.

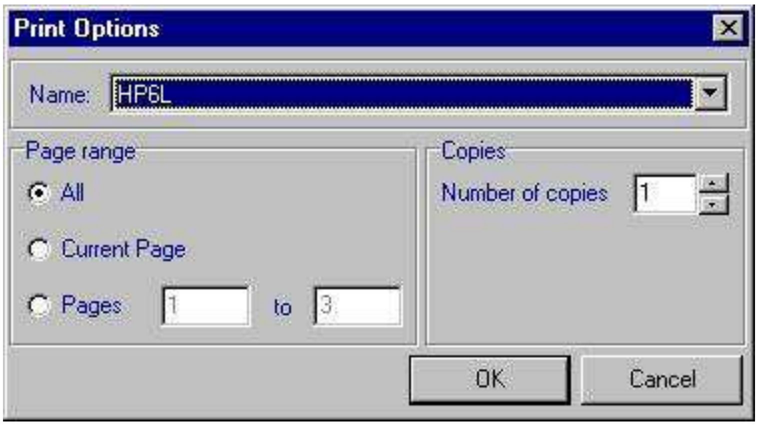
- From the report selection screen, select the print button.

- From the print preview screen, select the print

button

2. The Print Options screen will then appear. See Figure 33 below.
3. Select the printer, the number of copies and the number of pages required.
4. Select OK and the report will be printed.

Figure 33 - Print options screen



11.2.3 How to Save a report as an image to Disk

You can save a report to disk from the print preview screen.

1. From the print preview screen select the save icon.
The system will display the Save image Option. See

2. Figure 34 below

3. Complete the selections for: Select this page only, all

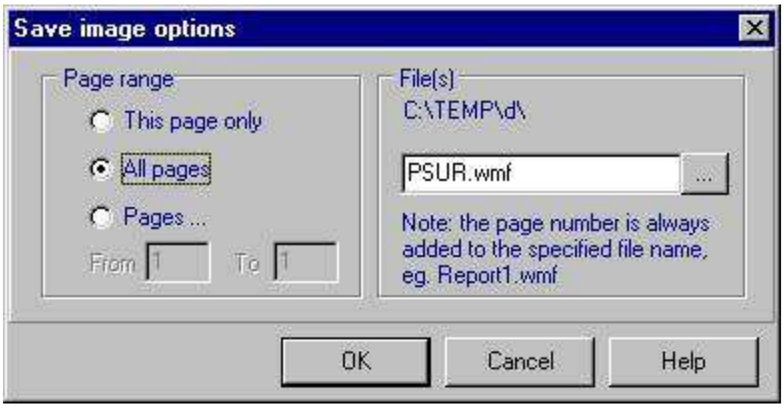
- **Page Range** pages or enter a page range.

- **File(s)** This is the name of the ***!If you are operating under***

file where the report will ***CITRIX, your local drive will*** be
saved. The system will ***not show as C. Please check*** create
a separate file for ***with your system*** each page of the report.
administrator for the name of your local drive.

4. Select OK, for the report to save. The system will confirm that the save has been successful.

Figure 34 - Save image options



11.2.4 How to Send a report to Word

You can export the file to Word from the print preview screen.

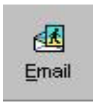
1. From the print preview screen select the Word icon.

2. The system will open up a new document in Word and import the report into the document. PV-Works (vet) also includes the Case Reference.

11.2.5 How to Send a report via the E-mail system

You can send the report via the e-mail system from print preview.

1. From the print preview screen select the E-mail icon.



2. You must save the report as an image before the system will send an e-mail. See How to Save a report as an image to Disk on page 50.
3. Once you have created the image files, PV-Works (vet) will load the e-mail system, open a new message and include the report image file(s) as an attachment(s).

11.3 Report Approval

The report approval function is an option that builds upon the Mandatory Data checks to provide a mechanism by which cases must be approved formally before official regulatory reports may be generated. Prior to this approval, data from a case may be presented in draft regulatory reports and may be included in any internal report that is generated.

Once a case has been approved for reporting (and only after such approval), an official report may be generated in the format of any of the PV-Works (vet) regulatory reports. In other words, the approval of reportability is an indicator of a case being ready for global reporting.

Customers can user 'report approval' as a Quality Control Review process.

You can approve a case

1. From the main screen select the **Report | Report Approval** menu option.

2. From within a case by clicking the 'Report Approval' icon

A case can not be approved if any 'mandatory' fields are empty. These fields will be shown with a status of 'error'.

11.4 Create Regulatory Submission Function

In handling adverse event cases on a regular basis, there are occasions when the user wishes to print the same single case report for a group of cases. The function to handle this is called 'Create Regulatory Submission'. Once the reports have been submitted, they may be marked as such in a single operation.

11.4.1 Creating a submission of multiple cases

You can run 'Create Regulatory Submission'

1. From the main screen select the **Report | Create Regulatory Submission** menu option.

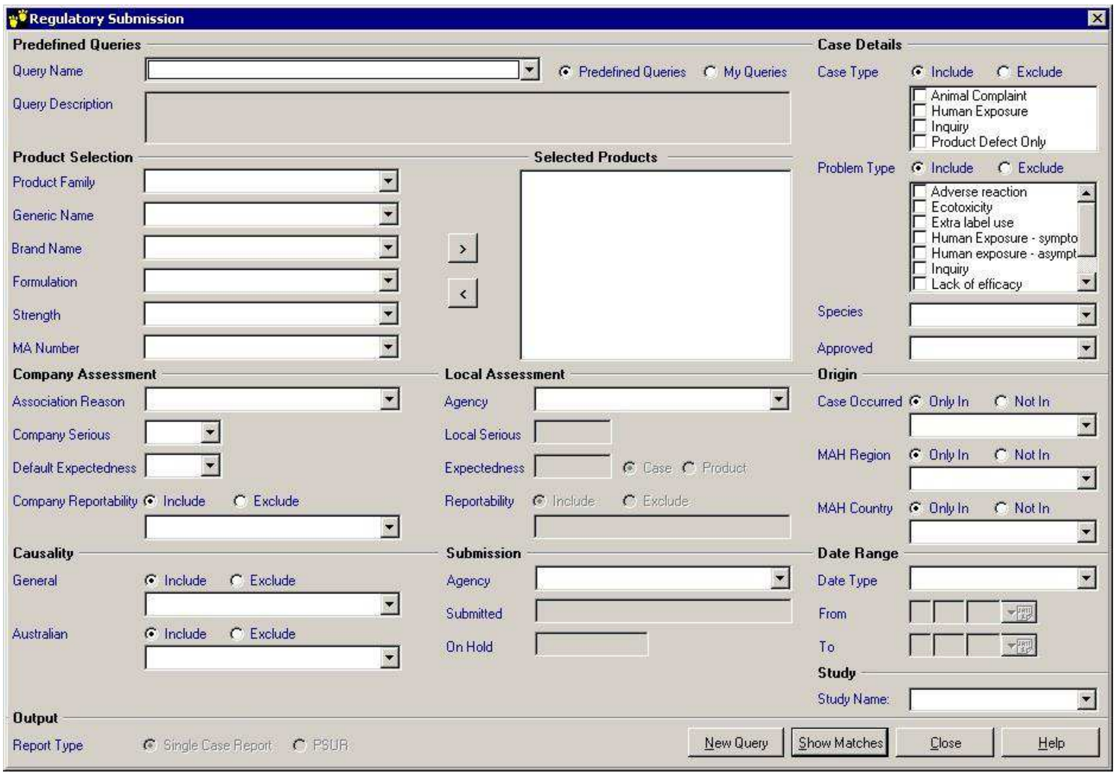
✐ ***The screen in Figure 35 may seem daunting at first but its most common use is actually very simple.***

✐ ***The System Administrator will set up several pre-defined queries that reflect the most common usage.***

2. Select a pre-defined query from the Query Name drop down list. The use of a pre-defined query makes all other selections non-editable.

3. Click 'Show matches'

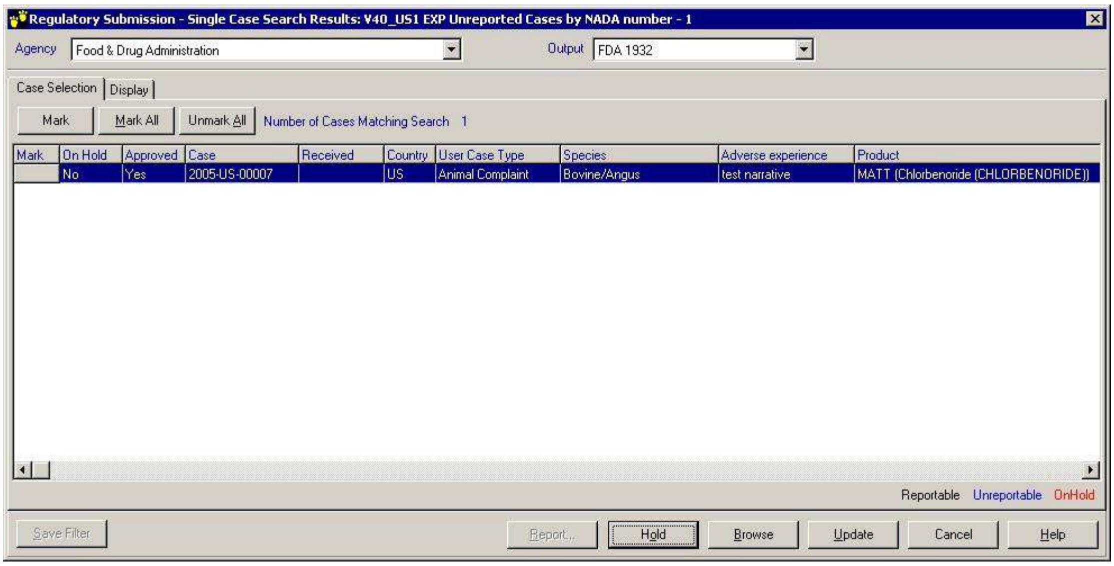
Figure 35 : Create Regulatory Submission Screen



4. Some queries may ask the user for other filter criteria eg

5. The cases that match the query are those that need to be reported. These are shown on a screen such as Figure 36.

Figure 36 : Multiple Cases that need to be reported

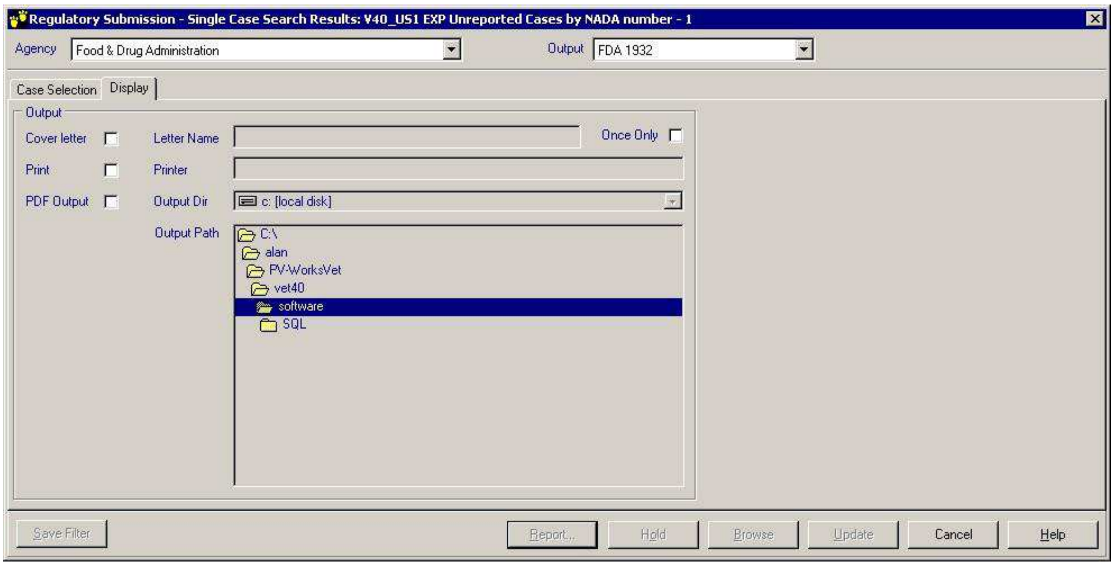


The agency and report type will be defaulted according the user's location

6. Click 'Mark all' to select all cases in the display

7. Review the 'Display' options in Figure 37

Figure 37 : Multiple Cases – Display options



8. Select one or more of the outputs / methods:
   - Cover letter – a letter generated from a user template to accompany the reports to the agency
   - Print – print letter (optional) and reports to the printer. Printer can be selected.

- PDF output – create a pdf file containing the letter (optional) and reports. The folder in which the pdf file is created may be defined.

9. Click 'Report'

NOTE: The 'report' button is not available until the destination agency, report type and one or more cases have been selected.

Each submission run is given a unique name

11.4.2 Recording a submission of multiple cases

Following a run of the 'Create Regulatory Submission' function, the user will review and then submit the reports. Once this is done, the user can record this fact in all of the cases in the submission in a single step:

1. From the main screen select the **Report | Record Regulatory Submission** menu option.

2. Select 'Single Report Submission'

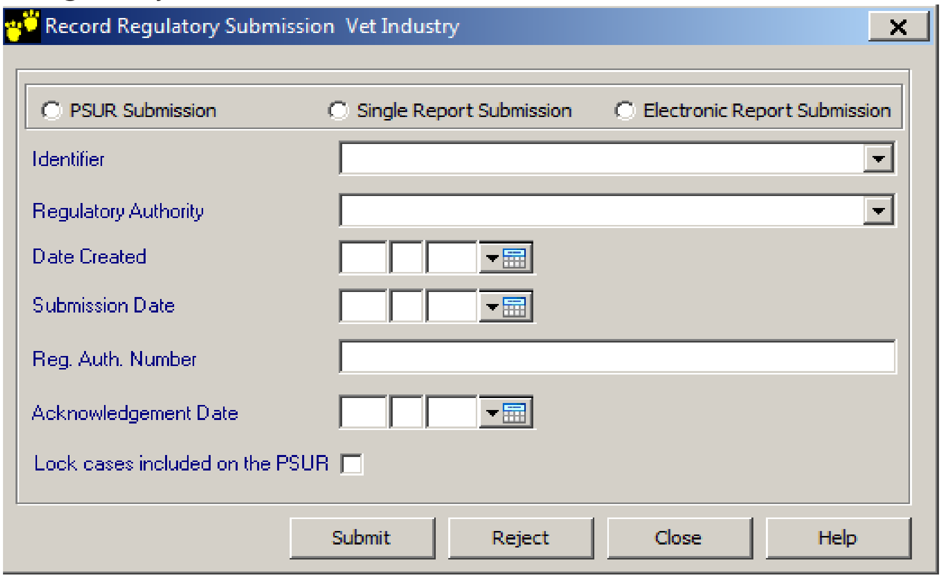
3. Select the Identifier from the drop down list. (The Regulatory Agency is selected automatically).

4. Enter the Submission Date

5. Click 'Submit'

If a submission that was created is not to be sent to the agency, it may be deleted using the 'Reject' button

Figure 38: Record Regulatory Submission



11.5 Periodic Safety Update Report

The 'Periodic Safety Update Report' (PSUR) is created with a function that is virtually identical to 'Create Regulatory Submission' as described in section 13.4.

11.5.1 Creating a PSUR

You can run 'Create PSUR Submission'

1. From the main screen select the **Report | Create Regulatory Submission** menu option.

The screen is identical to that in Figure 35 but with 'products' and 'date range' fields highlighted as these are mandatory.

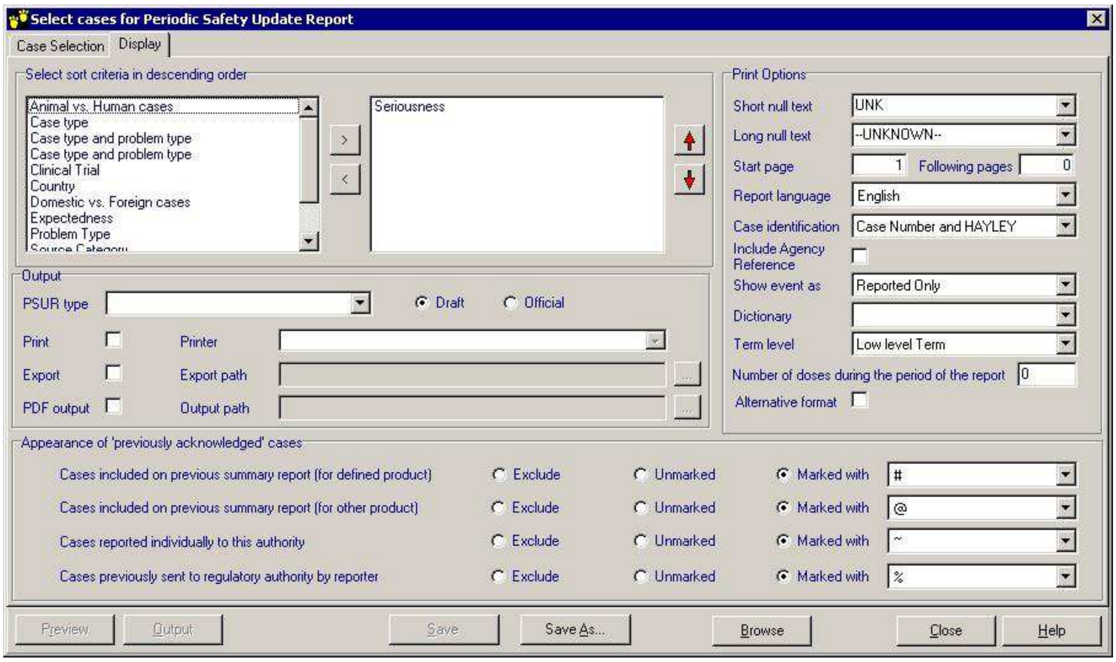
2. Select a product and enter a valid date range – typically case received.

3. Click 'Show matches'

4. The 'Show Matches' screen is identical to 'Create Regulatory Submission' as described in section 13.4. Select the agency to receive the PSUR.

5. Review the 'Display' options in Figure 37

Figure 39 : PSUR – Display options



6. The user must select the PSUR type – eg EU or Australian and the output destination (printer or pdf file)

7. The user may set the following options:
   - Sort sequence of cases
   - Appearance of 'previously acknowledged' cases, ie suffix character added to the case number to indicate previously submitted cases
   - Print options eg how to show the event and case number

8. Click 'Preview' or 'Print'

✐ ***Each submission run is given a unique name***

11.5.2 Recording a submission of a PSUR

Following a run of the 'Create Regulatory Submission' function, the user will review and then submit the reports. Once this is done, the user can record this fact in all of the cases in the submission in a single step:

1. From the main screen select the **Report | Record PSUR Submission** menu option.

2. Select 'PSUR Submission' in the same screen shown for 'Create Regulatory Submission'.

3. Select the Identifier from the drop down list. (The Regulatory Agency is selected automatically).
4. Enter the Submission Date
5. Click 'Submit'

If a submission that was created is not to be sent to the agency, it may be deleted using the 'Reject' button

12 Letter Writing

PV-Works (vet) has a facility for producing standard letters from case information. The letter templates are set-up by the System Administrator. The templates can be for any standard document e.g. standard letters, memorandum or facsimile messages.

12.1.1 Creating Letters

12.1.2 How to select and print a letter template from the main screen

You can select a letter template from the main screen by:

1. Selecting the **External** menu from the main screen and then choose **Letter Writing**

or

Click the Letter Writing icon from the main screen

2. Choose the sub-menu option '**Create Letter**'

The Letter template screen will be displayed, see **3.** Figure 40 below

12.1.3 How to select and print a letter template from within a case.

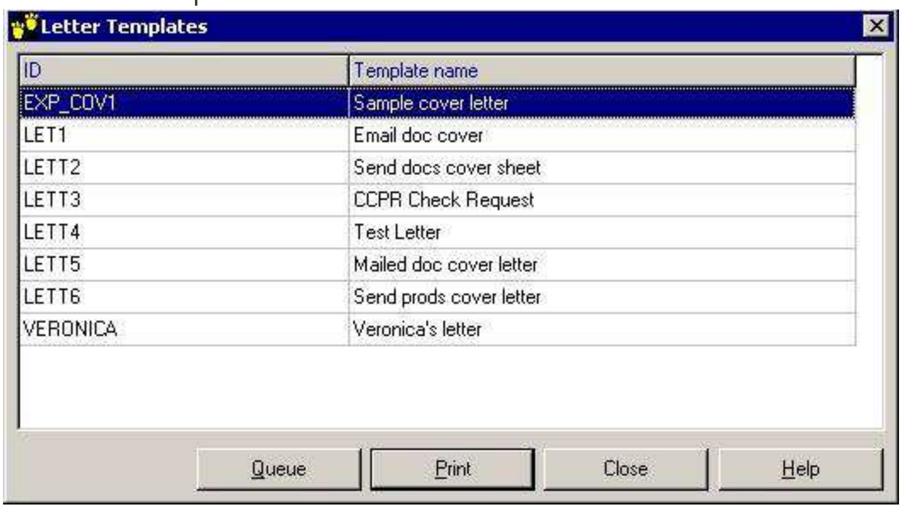
You can run a report from the Data Entry/Update screen by:

1. Select the Letters Icon from the top left hand of the screen

The Letter template screen will be displayed, see

2. Figure 40 below

Figure 40 - Letter Templates



ID	Template name
EXP_COV1	Sample cover letter
LET1	Email doc cover
LETT2	Send docs cover sheet
LETT3	CCPR Check Request
LETT4	Test Letter
LETT5	Mailed doc cover letter
LETT6	Send prods cover letter
VERONICA	Veronica's letter

3. Highlight the letter template name you wish to run and select Print.

4. The confirm message will appear.

- If you wish to preview the letter template in word or amend the letter template select **Yes** to preview. PV-Works (vet) will then display the letter with the case data selected.

- If you do not wish to change/preview, then select **No**, and the letter will print direct to your printer.
- Alternatively you can add the letter to a queue for later printing

12.1.4 How to edit the letter when it is created

Although the letter has been generated from a template, it is possible to edit it during its creation step

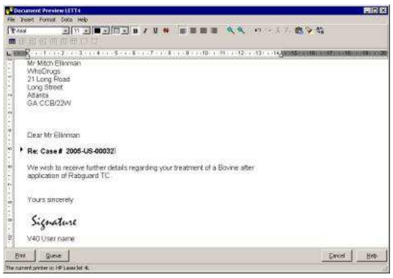
1. Your graphic signature may be added to the letter in the 'signature block'.

✎ ***Note for security reasons and unlike reports (section 13.1) it is not possible to add the signature*** of ***any other user.***

2. You can select the recipient of the letter (if appropriate, ie defined in the template). The pop up screen will display all contacts recorded in the case for selection.

✎ ***The recipient MUST be a contact defined within the case. You cannot send a letter to an 'outsider'.***

3. The letter is displayed in a Word-like word-processor window. The text can be edited.



✎ ***While you can edit any text, including that derived from the database, changes made to the letter will not alter the database itself***

✎ ***Note that your signature is not shown in the letter preview. This is only added when the letter is printed***

The editing operations that are available are the most common ones for a word processor and include:

- Insert / delete
- Cut / copy / paste
- Font change
- Bullets and numbering
- Basic table function

4. When the letter has been edited, the user should click either.

To print the letter.

To queue the letter for printing later.

To close the preview without printing or queuing.

12.2 Managing the Letter Queue

You can select a letter queue from the main screen by:

1. Selecting the **External** menu from the main screen and then choose **Letter Writing**

or

Click the Letter Writing icon from the main screen

2. Choose the sub-menu option '**Letter Queue**'

The list of letters displayed is restricted to those created by users in your location

The list can be filtered to assist processing using the 'Filter Queue BY' criteria at the top of the screen.

3. Select letters by

- Clicking the check box to the left of the letter in the grid, or

- Select a row and click 'Mark'
- Click 'Mark All'

4. From this screen the user may

- Select the printer to be used
- Print the selected letters
- Preview a letter
- Delete a letter from the queue
- Return to the case that generated the letter
- Create an 'Action Board' task, e.g. to ask for an amendment to the letter

Note: On printing the System Administrator can cause an electronic copy of the letter (as a pdf file) to be kept permanently in the PV-Works Document Repository.

5. The user may also look at a 'letter archive' and search for a letter than needs to be re-printed (e.g. due to printer error). ***Note unless otherwise set by the System Administrator, all letters are kept for 7 days after printing. After this period the letter is deleted.***

13 Case Management

13.1 Selecting Cases

To view the case details or to amend the case details the user needs to select the case required and make this the case displayed on the main screen. There are a number of options to select your case.

If you know the case reference number you can:

- Select the case by using the case mask

If you have recently viewed this case you can:

- Select the case from the most recently used cases, available from the file menu or as a specific main screen grid query

If you know only partial details of the case, or wish to find cases matching a range of criteria you can:

- Use the searching functionality on the main screen grid

- Use the Find Case button (applicable if the main screen grid is not deployed)

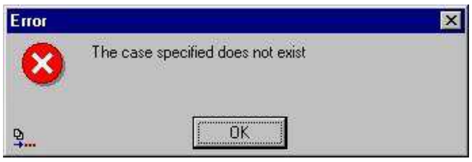
13.1.1 How to select a case by using the case mask

The case mask is found on the top right hand side of the screen:

The case mask can be changed by your system administrator to include various data types. In this example the case mask is compiled of the following fields.

1. To select a new case:
- Country Type in the country code or select from the drop down list
- Year Enter the year or use the buttons to select a year
- User Initials Type in the initials
- Unique Case Reference Type in the unique reference number

2. When you have completed the fields, either press the Enter key or  to select the new case.
3. The current details for the case will be displayed on the main screen.
4. If you have typed in an incorrect case reference, the system will display this message:



5. The system will clear the case mask ready for you to type in the details again.

13.2 Main Screen Grid Querying

The main screen grid allows searching in the following ways:

- 'Main screen grid queries' are queries written by Assured and / or the System Administrator that handle most daily query needs. These are extremely flexible and make searching very simple.

- 'Build A Query' is a tool that allows you to create a query yourself, defining each filter criterion in turn. This is useful for ad hoc situations.

13.2.1 How to search for a case using main screen grid queries

The main screen grid contains a list of fixed queries (provided by Assured or the system administrator) grouped together in a series of blocks on the left hand side.

The Grid system offers a flexible approach to querying the database. Not only is it capable of running any query and thus accessing any database field, but the actual data items displayed in columns may be configured. As a consequence the resulting grid of data to be retrieved and displayed can be of any size. In order to control the overall performance of PV-Works and prevent a single user 'taking over' the database, two checks have been added:

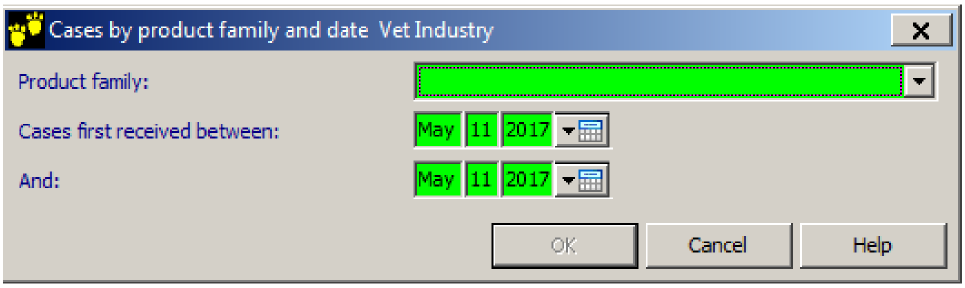
a) a warning that more than 'x' cases have been found as a result of the query. After acknowledging the warning, the user may continue with the query, but is now aware that the display of results will not be instantaneous

b) an 'error' that states that more than 'y' cases have been found as a result of the query and that this is too many to process. This prevents a user running a query that consumes too many resources.

The values of 'x' and 'y' are controlled by the System Administrator via system options and will be set with local experience. In setting these values it should be remembered that this screen is a Find Case function; it is intended to bring back a workable list of cases.

Grid queries may be configured to present the user with a parameters screen, to enter further search criteria:

Figure 41 - Grid Query Parameter Screen



Query results will be displayed in the main grid:

Figure 42 - Main Grid Query Results

Drag a column header here to group by that column

Case number - Version	Date first received	Case owner	Case type	Brand name	Species	Country of occurrence	Product Problem type	VedDRA PREF (all)
2010-US-00027	20-Apr-2010	US PV User 41	Animal Complaint	AlphaCream America		USA		
2010-US-00014	12-Apr-2010	US PV User 41	Animal Complaint	AlphaCream America		USA		
2010-US-00049	18-May-2010	US PV User 41	Animal Complaint	AlphaCream America	Bovine	USA	Adverse reaction	
2010-US-00015	12-Apr-2010	US PV User 41	Animal Complaint	AlphaCream America		USA		
2010-US-00022	15-Apr-2010	US PV User 41	Animal Complaint	AlphaCream America		USA		
2010-US-00039	28-Apr-2010	US PV User 41	Animal Complaint	AlphaCream America		USA		
2010-US-00025	15-Apr-2010	US QA User 41	Animal Complaint	AlphaCream America		USA	Adverse reaction	
2010-US-00044	6-May-2010	US PV User 41	Animal Complaint	AlphaCream America	Canine	USA		
2010-US-00012	12-Apr-2010	US PV User 41	Animal Complaint	AlphaCream America		USA		
2010-US-00037	28-Apr-2010	US PV User 41	Animal Complaint	AlphaCream America	Bovine	USA		
2010-US-00048	18-May-2010	US PV User 41	Animal Complaint	AlphaCream America	Bovine	USA	Adverse reaction	Blood dyscrasia NOS;
2010-US-00035	23-Apr-2010	US PV User 41	Animal Complaint	AlphaCream America	Bovine	USA	Product defect	

Once a query has been executed the user can use the power of the grid to manipulate the results as follows:

- Sorting each column (ascending or descending) by clicking the column header
- Grouping the data by moving one or more column headers into the grouping band
- Re-ordering the columns by dragging the column header to a new position
- Filtering the display based upon the contents of each column using the dropdown list

In addition the user will be able to control the data elements presented in the grid, by picking from a standard list of available data fields. When a new query is added (either to the predefined query list, or via the build-a-query screen) the default layout specified by the System Administrator (or shipped by Assured) will be applied. Having changed this default display list for a particular query, the user is able to apply the same display layout to another query.

Grid results can easily be printed, exported or emailed using processing options at the bottom of the main screen:

When the user closes PV-Works, the system remembers the query that was last displayed on the Grid Main Menu Screen. When PV-Works is re-started it will display the same query results set for the user; or more accurately it will re-run the same query that the user ran previously to display data. This may mean that the results set will be slightly different as it will be updated with any case changes since the user last logged in.

13.2.2 How to search for a case using Build A Query

You can Build your own Query by:

1. Select the My query builder option in my queries block

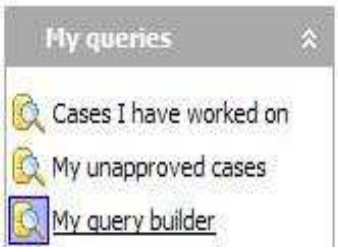
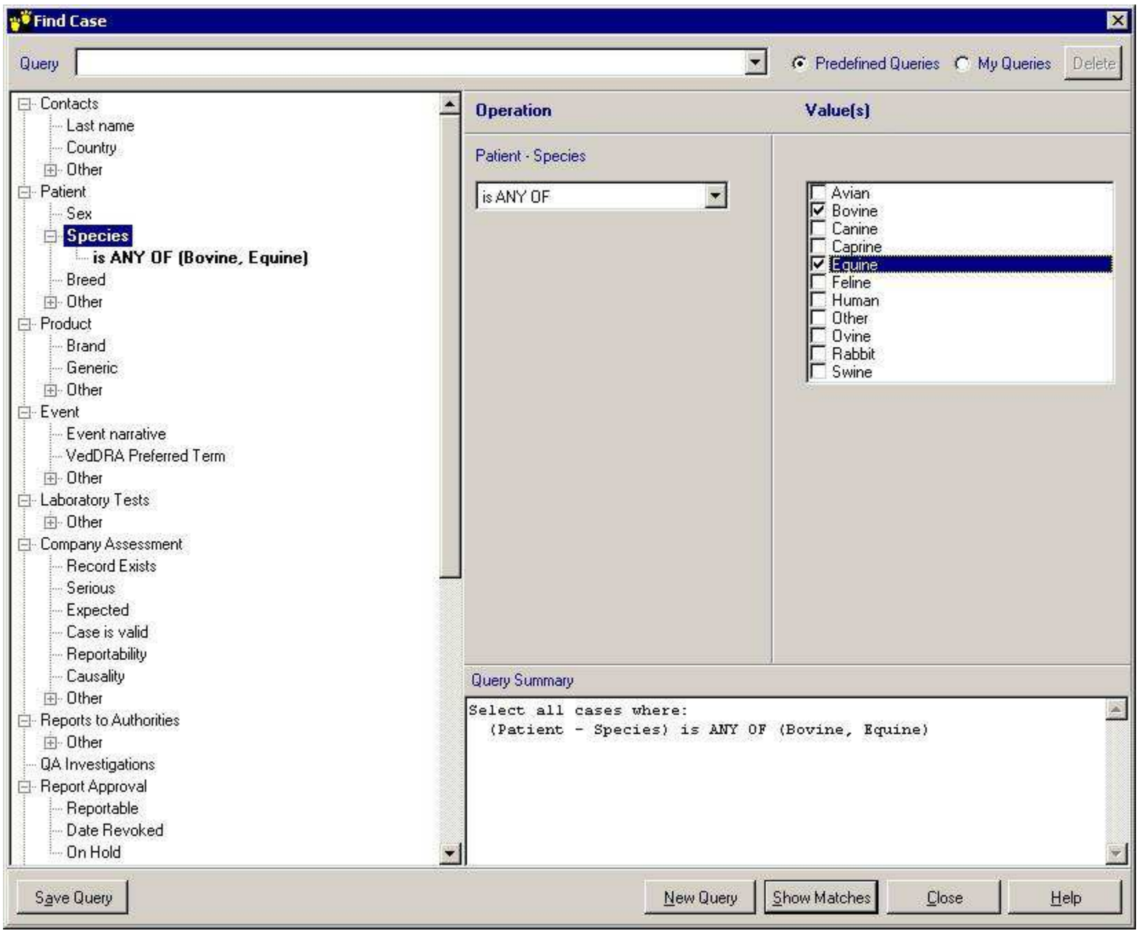


Figure 43 - Find Case Screen



It is also possible to select and run a Pre-defined Query from this screen

2. In the left hand window is a list of data fields that can be selected as filter criteria. This list is flexible and is controlled by the System Administrator. In its standard set up it mimics the data entry screens on the principle that 'if you know where the data is entered, you know where to find it for searching'.

   Select a field by highlighting it

3. The Operation section and Value(s) section will reflect the type of field selected.

   Operations depend on the field type:

   Text fields: =, not =, CONTAINS, EMPTY, NOTEMPTY, START

   Numbers: <, <=, <>, =, >, >=, BETWEEN, NOTBETWEEN

   Dates: <, <=, <>, =, >, >=, BETWEEN, NOTBETWEEN

Codelists: <>, =, ANY, EMPTY, NOT =, NOTEMPTY

The Values section will display a data entry field appropriate to the field type, i.e. a drop down list for a codelist, a date field for a date etc.

At the foot of the screen is a pseudo English description of the query. You can cut and paste this to another document.

Multiple filter criteria are joined with an AND construction. The only facility for OR is the 'ANY' operation for codelists

4. Once you have completed your selection, press Show Matches to produce the list of cases matching your search criteria.

5. The system will then display the Case Search Result Screen. From here you can select any of the cases listed to be your current case. Please see How to use the Case Search Results Screen below.

6. The other options available from the Find Case Screen are:

- New Query - This will clear the screen of any entered search criteria for you to enter new details
- Close – Closes the Build a Query function without searching
- Save Query – Allows you to save the filter criteria for re-use

A saved query is personal and can only be used by yourself. If you have created a query that you feel should be used more widely, pass the name that you have given it on save and ask your Systems Administrator to convert it to a Pre-defined Query.

A saved query may be selected by clicking the My Queries ***radio button and selecting from the drop down list***

A saved query may be deleted by selecting it and clicking the Delete button

- ***Queries from the 'Build A Query' function will probably offer poorer performance than a Pre-defined Query as the System Administrator has more opportunity for tuning. This is not to say that Build A Query is slow!***

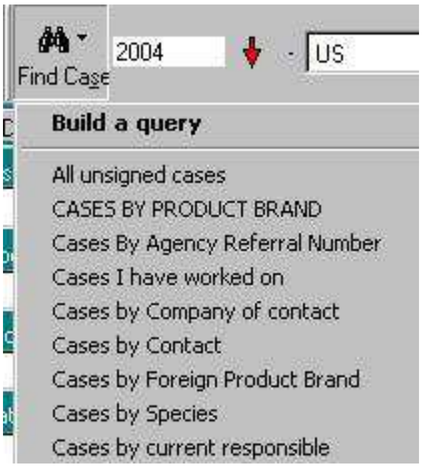
- ***If the query is likely to return more than 1000 cases, the system will give you a warning and an opportunity to abandon the query. The logic here is that you are trying to Find Cases to work on; if you are returning more than 1000 cases, it suggests that the filter criteria need to be refined***

13.3 Find Case Button

If the main screen grid is not deployed, a standard find case function also allows the execution of pre-defined queries, and access to the build a query function:

1. Clicking the 'Find Case' icon on the Main Screen.

2. A list of Pre-defined Queries will be displayed. ***The exact list displayed will depend on the set of predefined queries that have been implemented – and your location***



3. Select a pre-defined query

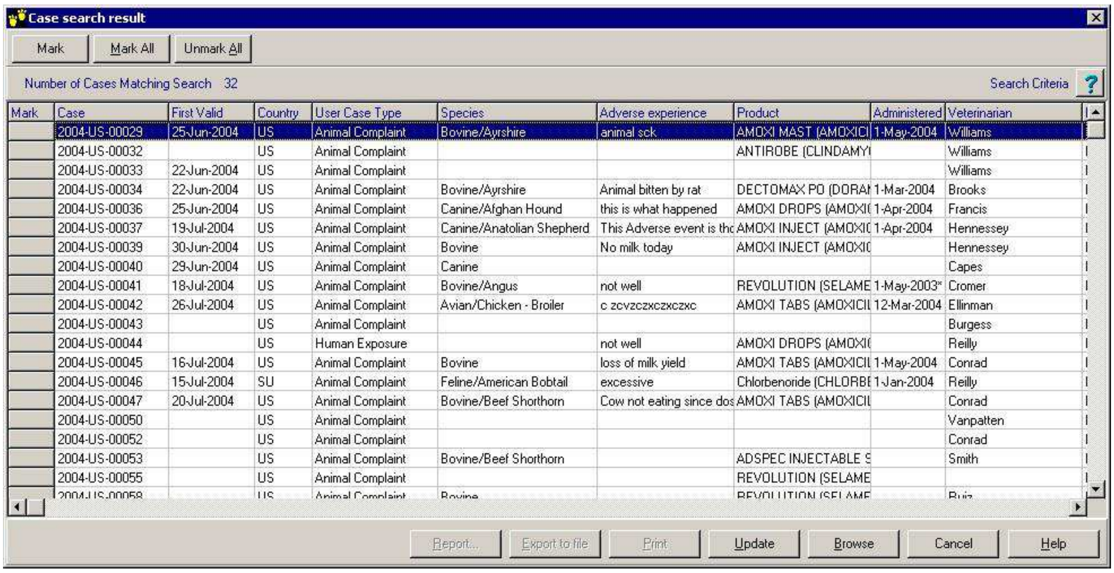
4. Some (but not all) pre-defined queries will ask for further filter criteria. There may be one or more fields to enter on a pop up screen. Enter the relevant data and click OK

5. The 'Matching Cases' screen is displayed. See below for a description of its use

13.3.1 How to use the Case Search Results Screen

The results of any ‘find case’ are shown in the Case Search Results Screen. Please see Figure 44 below.

Figure 44 - Case Search Results Screen - Find Case



The following options are available from the case search results screen:

- Search  Criteria allows the user to view the search criteria entered on the previous screen.
- Mark mark an individual case for export or reporting
- Mark all Mark all cases in the list for export or reporting
- Unmark all Unmark all marked cases in the list
- Report Loads the Single Case report selection screen () and allows the user to create a report for each marked case, e.g. an FDA 1932, a CVMP, a Crystal Report etc.

  Only cases that have been ‘marked’ may be reported

- Export to File Allows you to export data to a comma-separated value file (.csv). This can be used with other software such as SAS and Excel

- ***Only cases that have been 'marked' may be exported***

- ***Once data has been exported to a csv file, it is no longer protected. It can be amended without an audit trail. Once outside of PV-Works, the system can take no responsibility for the data or its processing***

- Print This previews a simple report of all the marked cases in the list
  - ***Only cases that have been 'marked' may be reported***
- Update Case This selects the case highlighted in Data Update Mode. After 'update' you are returned to this list so that you can process another case.
- Browse Case This selects the case highlighted in Data Review Mode. After 'browse' you are returned to this list so that you can process another case.
- Cancel Will cancel this screen and return you to the previous screen
- Help Accesses the on line help system

13.4 Case Linking

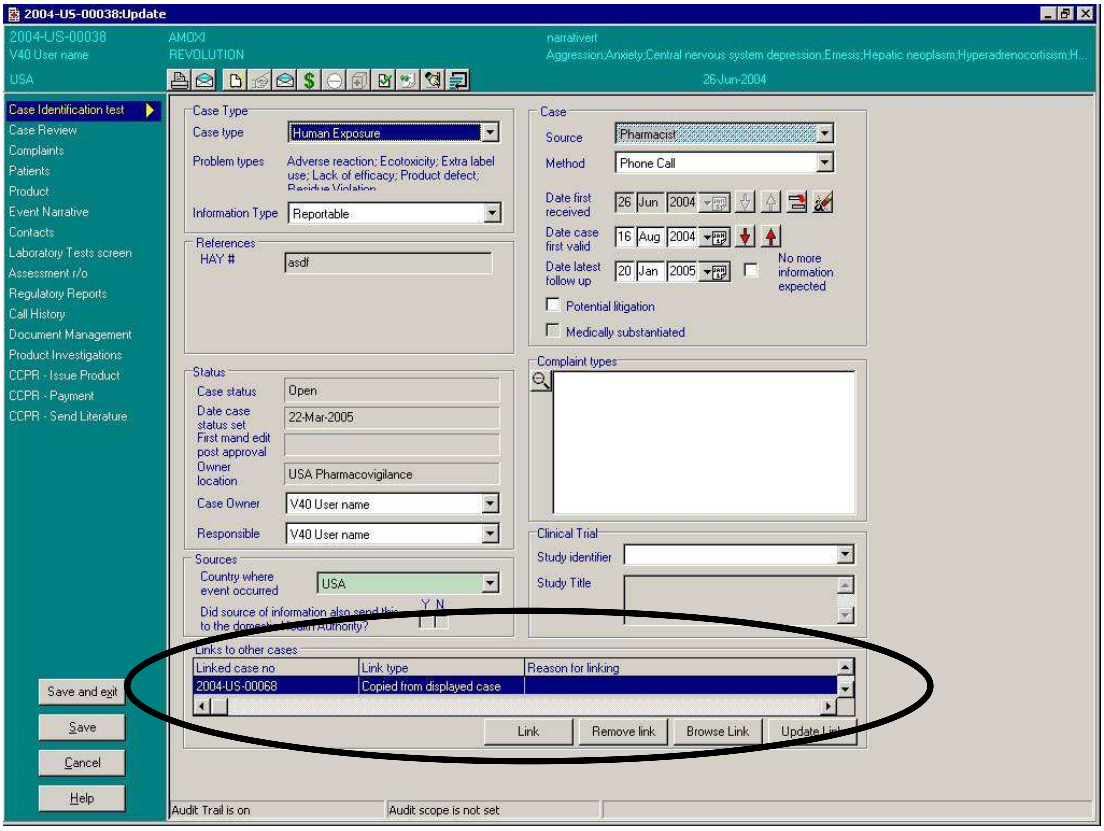
PV-Works (vet) can record permanent links between cases for reasons such as:

- Animal and human cases from related exposures
- Suspected duplicates

Case links are shown on the Case Identification screen of the Data Entry / Update module. See Figure 45 below.

Each case may be linked to as many cases as required. The user must provide a reason for making the link. PV-Works (vet) will record the link in all cases that are joined together so that each case references the others.

Figure 45 - Case Linking



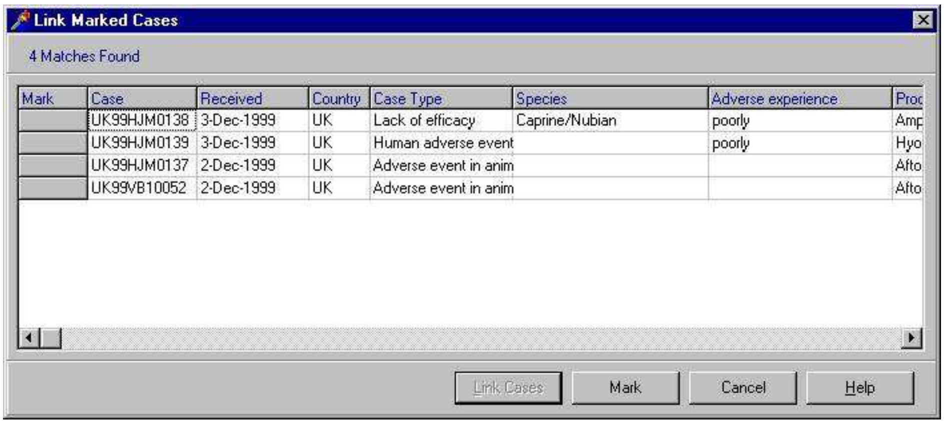
13.4.1 How to Link Cases

1. You can access the Link Cases option from either
   - the Data Entry/Update screen, Case identification use the Link button  ***or***
   - from the menu options Data followed by **Link Case.**

2. The system displays the Find Case - Linking records search screen. This screen has similar functionality as the Find Cases search screen.

3. Once you have completed the search screen the system displays any matching cases on the Link Marked Cases screen.

Figure 46 - Linked Marked Cases



4. Highlight the case you wish to link using the mouse, then select **Mark**. The system will place a red cross next to the record you are going to link. .
5. Continue to select and Mark as many cases as you wish to link.
6. If you need to de-select a record, highlight the case with the mouse and then select **UnMark**.
7. Once you have selected all of the cases you need to link, select **Link Cases** and the link cases screen will appear. See Figure 47 below.

Figure 47 - Linked Cases

8. This screen needs to be completed for each case being linked, selecting **OK** moves the system onto the next record to be linked. Both of the fields required are Mandatory.
   - Type Type of case linking e.g. related human exposure
   - Reason Reason why they are being linked.

9. Once you have completed all of the links the system returns to the previous screen.

13.4.2 How to Remove Linked Cases

1. You can only access the Remove Link Cases option from the Data Entry/Update screen, Case identification.
2. Highlight the case you wish to remove and select the Remove Link button 

3. The system will ask you to confirm removing the link between the two cases. Selecting Yes removes the details from the screen and you can then repeat the process for further linked cases.

Figure 48 - Remove Link Confirmation Message

Note from the Case Identification you can use the link to browse the case to which the current case is linked

13.5 Case Locking

When a case has completed its processing it is possible to 'lock' the case so that no further data amendment can occur. PV-Works (vet) allows a user to lock any case. The 'Case Lock' function is found on the File menu of the Main Menu screen.

When a case is locked the phrase Case Locked appears on the Main Menu screen together with a padlock symbol.

The case may still be reported and reviewed but no data amendments are possible.

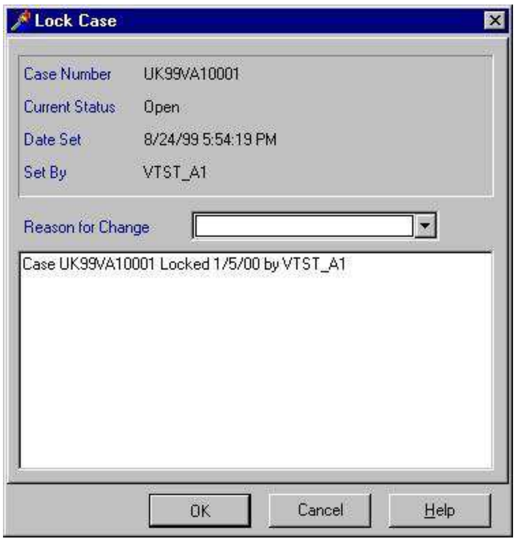
A locked case may be 'unlocked' so that data can be edited.

The Systems Administrator should ensure that only privileged users are able to lock and unlock cases. Different access rights may be granted to these two functions.

13.5.1 How to Lock a case

From the main screen select **File** and **Lock Case.** The Lock/Unlock Case screen appears. See Figure 49 below.

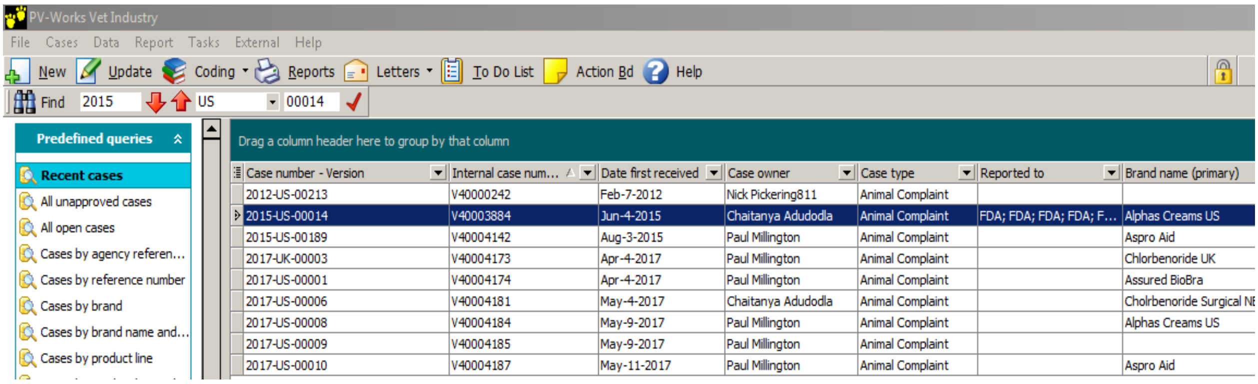
Figure 49 - Lock/Unlock Case Screen



2. The system creates a history of when the case was locked. You have to select the Reason for change.

Selecting **OK** takes you back to the main screen but displays a padlock on the right hand side to show that the case is locked. See Figure 50 below.

Figure 50 - Case Lock – Padlock



13.5.2 How to Unlock a case

From the main screen select **File** and **Unlock Case** ***or*** select the Padlock on the right hand side of the main screen. See Figure 50 above.

The Lock Case screen appears. See **Figure** 49 above.

Select the Reason for change.

Selecting **OK** takes you back to the main screen and the padlock has been removed.

13.6 Case Versioning

Users may wish to take 'snapshots' of the data in a case at a particular time so that subsequent reference may be made to the data at a critical point in the process. A typical example of this is the moment when a regulatory report is sent to an authority, thus allowing the company to answer any queries on this case based on the information known at the time of the report as well as on the latest data.

Changes to the case are made to the master version of the case and are not replicated in any of the 'snapshots'.

✐ ***The 'Master Version' or 'Main Version' of the case is always Numbered -0 with version 1 being the oldest version. You can only make any changes to version 0 all other versions are locked.***

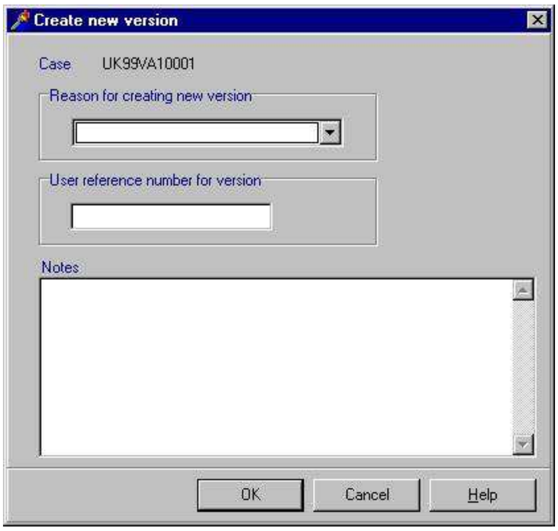
13.6.1 How to Create a New Version for a case

1. From the main screen select **File** and **Version** and the Create New Version Screen is displayed. See Figure 51 below.
2. The following fields are available:

- Reason for creating new version *!Mandatory*
- User Reference for version
- Notes

3. Selecting OK, creates the version and returns the user to the previous screen using the created version. This version is locked. The version number is assigned automatically.

Figure 51 - Create New Version screen



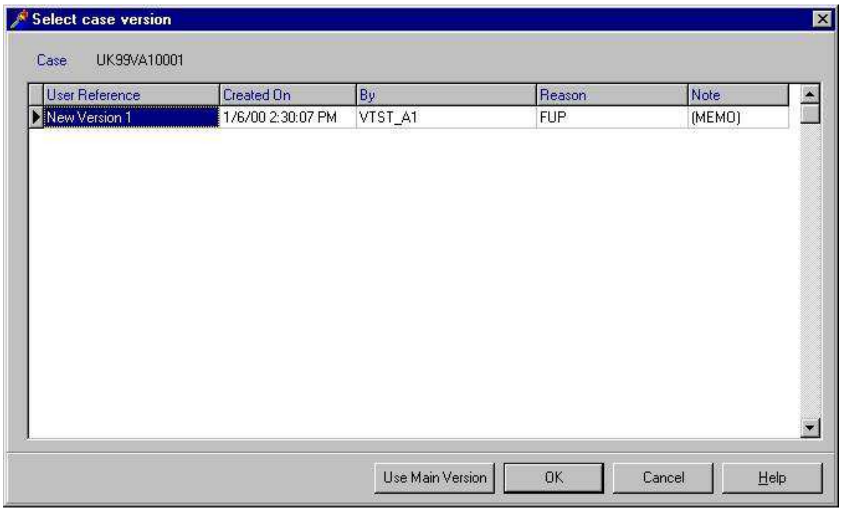
Note: Versions can be created automatically when a case is approved using the Report Approval function. (see section 13)

13.6.2 How to select a Version

If you wish to view a previous version or return to the main version PV-Works (vet) allows you to select the version you require.

1. From the main screen select **File** and **Select Version** and the Select Version Screen is displayed.

Figure 52 - Select Case Version



2. The system will display all of the versions for this case.
3. The NOTE field shows the text [MEMO] if any notes have been typed in. To read these notes, use the mouse to select the field and double click with the right hand mouse. The Notes pop up will appear and you can then read the full text.

4. From here you can:

- Select a previous version — Highlight the version you wish to use and select **OK.** The selected version will appear on the main screen.

  or

- Select the ‘Master Version’ or ‘Main Version’ — Select the Use Main Version Button. Version 0 of the case will appear on the main screen

13.7 Delete Case

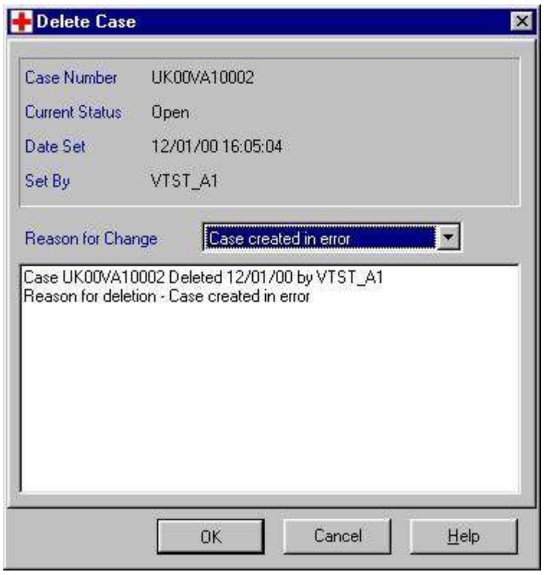
PV-Works (vet) provides the functionality to delete cases from the system. This option does not actually delete the case from the database but changes the deleted flag stored in the database on the case to **Yes** (the default is No). This case is then unavailable for queries, data entry and reporting activities.

If a case is deleted in error there is a Case Undelete option available to Systems Administrators only, this will restore the case to the database.

13.7.1 How to delete a case

1. Ensure that the case you wish to delete is being displayed on the main screen.
2. From the main screen select **File** and then **Delete Case**. The delete case pop up will appear. See Figure 53 below.
3. The screen displays the current case number and case status information.
4. You must select a **Reason for Change** from the drop down list.
5. The system will create a history of the case deletion.
6. Select **OK** for the case to be deleted.
7. The system will return to the main screen, but the details of the deleted case would have been removed.

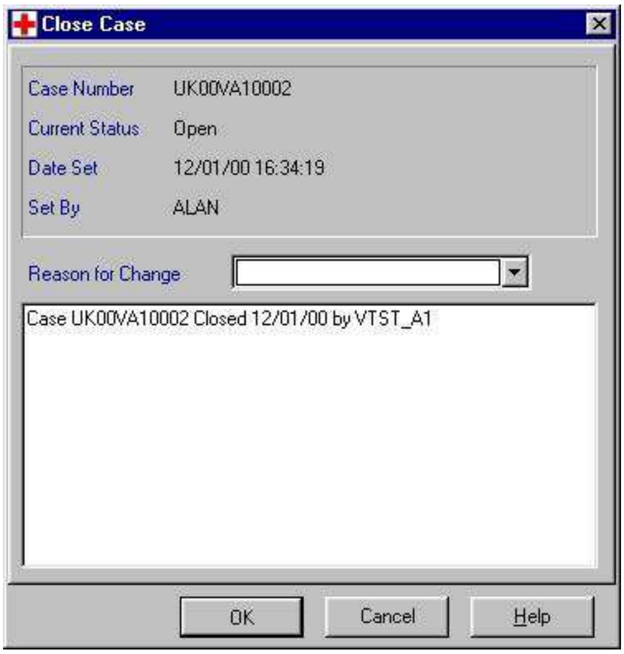
Figure 53 - Delete Case Pop up



13.8 Close or Re-Open a Case

PV-Works (vet) provides the functionality to close cases on the system. This changes the case status to closed and only then allows you to view the case in Data Review mode. For further information see section 11 Data Review on page 38

Figure 54 - Close/Re-open Case



13.8.1 How to Close or Re-open a case

1. Ensure that the case you wish to close/re-open is being displayed on the main screen.
2. From the main screen select **File** and then **Close Case /Re-open Case**. The close/re-open case pop up will appear. See Figure 54 - Close/Re-open Case above.
3. The screen displays the current case number and case status information.
4. You must select a **Reason for Change** from the drop down list.
5. The system will create a history of the case closure/re-open action.
6. Select **OK** for the case to be deleted.
7. The system will return to the main screen, but the status of the case will change to show closed or will revert back to open.

14 Duplicate Check

The Duplicate Check function can be used ahead of data entry. This allows the user to check for any possible duplicate cases in the system based on fields such as contact's name, product administered and date of administration.

Note that where data entry occurs via a telephone call this function is less likely to be used. For telephone based calls the user will enter the contact's details and the system will identify all cases that have been entered previously from the same caller. This prompts the user to recognise a potential follow up situation.

The Duplicate Check function enables the user to:

- Test to see if the case has been entered previously
- Display an existing case for modification

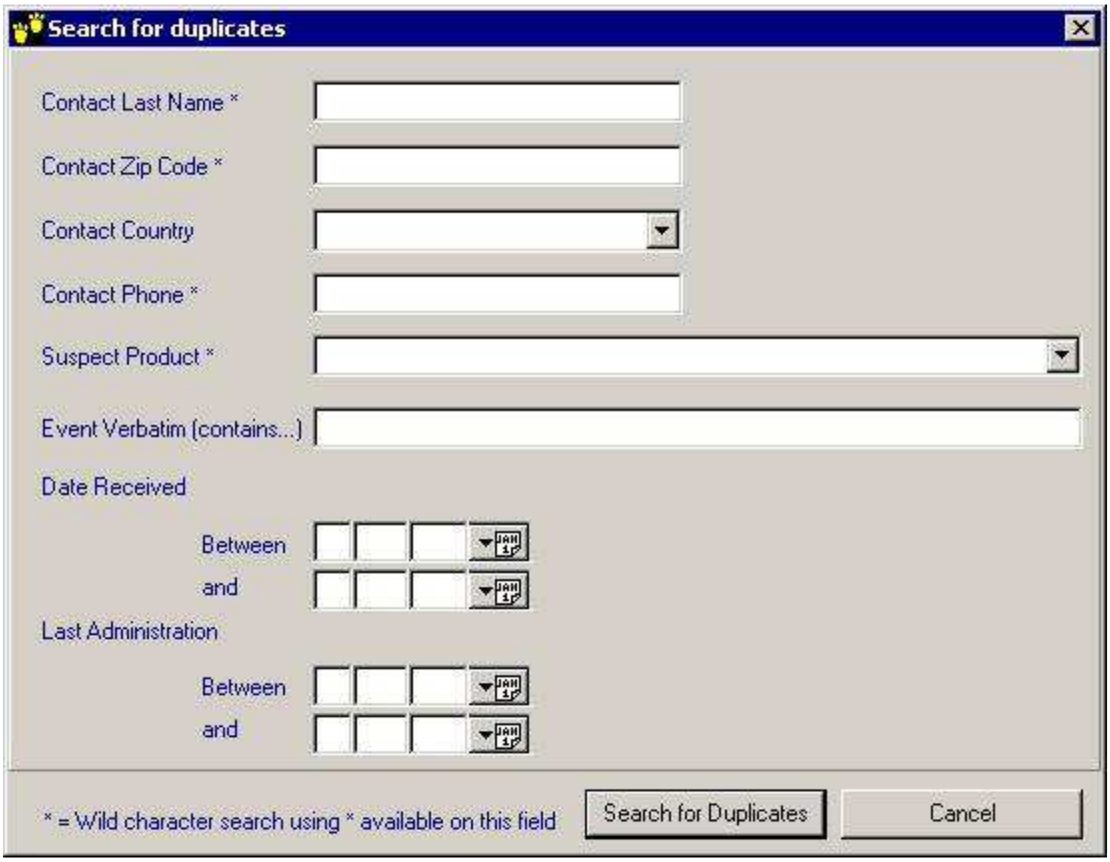
14.1.1 How to use Duplicate Check

1. You can access the Duplicate Check system

- From the main menu select **Data** and **Duplicate Check** ***or***
- Select the Duplicate Check icon from the main screen

2. The Duplicate Check pop-up screen will be displayed. See Figure 55 below.

Figure 55 - Duplicate Check Option



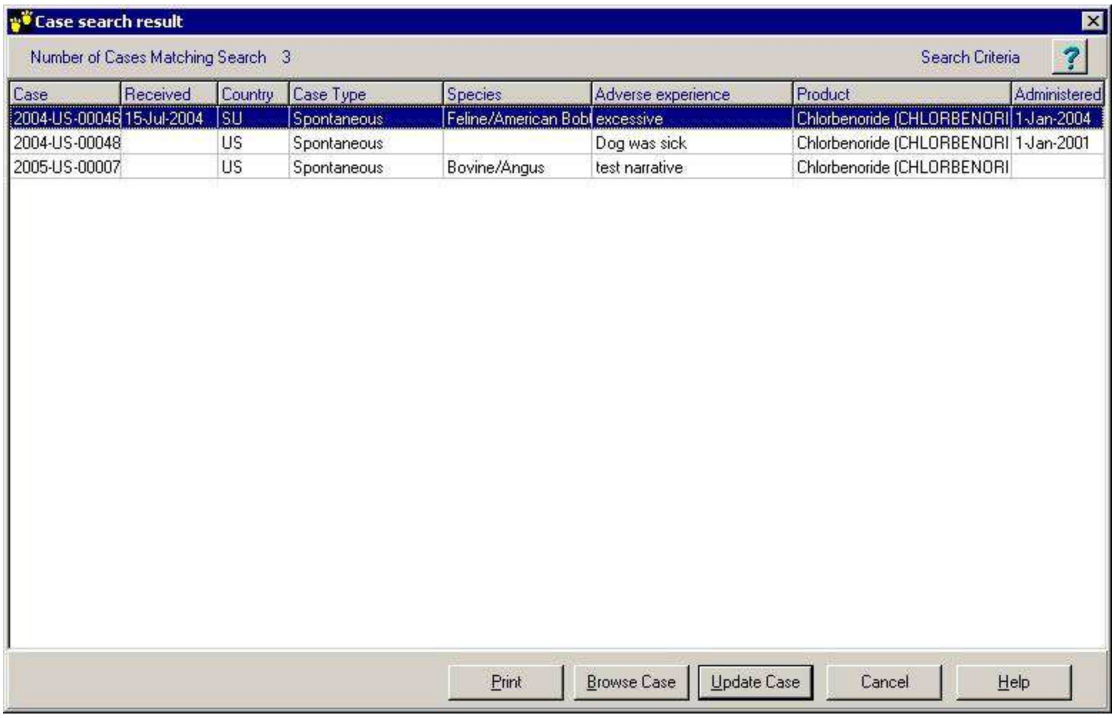
3. You can search for a duplicate by entering one or more of the fields shown in Figure 55

Note that any field marked with an asterisk supports wild card searches e.g. s* n will search for all names beginning s and ending in n.

4. Select the Search for Duplicate button to display the matching records. The Case Search results screen is then displayed. This screen has similar functionality as the Find Case results screen. ('Similar' in that it is identical with a few options omitted, eg export to file)

For further information on the option from this screen, please see How to use the Case Search Results Screen on page 65

Figure 56 - Case Search Results screen – Duplicate search



5. If the case you require is not displayed, select **Cancel** and the system will return you to the previous screen.

6. Select the **Update Case** to append / change the case information where a duplicate is detected

15 Audit Trail

PV-Works (vet) includes an audit trail function that is compliant with 21 CFR Part 11 and other quality standards.

✎ ***The audit trail is not switched on during initial case entry and only becomes active when the data is first committed to the database.***

✎ ***All case records in the database record the name of the user who created them as well as the date and time of creation***

✎ ***The implementation of the PV-Works (vet) audit trail means that any edits to the database are captured. This includes any changes made by upgrade scripts or the DBA. This applies to case data and configuration data.***

The PV-Works (vet) audit trail meets regulatory expectations, recording:

- name of user making the change (automatically set to the name of the logged on user)
- date and time change made (taken from the server rather than the user's PC to avoid time-travelling concerns)
- old value
- new value
- reason for change

All update screens, including those for case assessment, will show the status of the audit trail at the foot of the screen. See Figure 57 below.

Figure 57 - Audit Trail Status

15.1 Editing data with audit trail switched on

When the audit trail is active and the user makes a change to any field in the database via the Data Entry screens, PV-Works (vet) will prompt for a 'reason for change'.

15.1.1 How to Edit Information with the Audit Trail active

If the Audit Trail is switched on, the first change to a data field or notes text results in the Audit Trail window appearing. See Figure 58 below.

Figure 58 - Editing Information - Audit Trail Pop Up

The reason for change needs to be completed:

- Reason for change — Either select the reason for change from the drop down list ***or*** enter as free text ***or*** select a reason and edit it

✐ ***Once an 'audit reason' has been given, it is applied silently to all changes made in the same editing session, ie until the user clicks 'Save and Exit'***

✐ ***At any time the user may change the current audit reason by right clicking the mouse in any field and selecting 'Reset audit trail message'***

Select **Save** to save the Audit Trail details.

Select **Help** to access the online help.

If the user subsequently cancels all changes, then the audit trail record is not saved to the database.

15.2 Viewing the Audit Trail

From any Data Update screen data changes recorded in the audit trail for a single data item may be displayed.

15.2.1 How to view the Audit Trail

Highlight the appropriate field on screen, right-clicking the mouse and select **View audit trail**, the pop-up window is displayed in Figure 59 below.

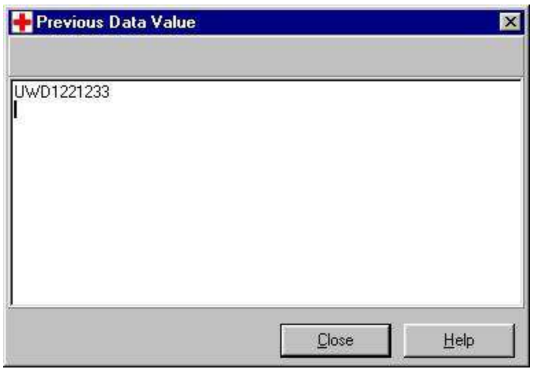
Changes recorded for the selected field are displayed in date order for the changes.

Audit trail changes are not visible until the case has been saved

To display more details about the previous value select  at the bottom left hand side of the pop up and the Previous Data Value pop up will appear. See Figure 60 below.

Figure 59 - Audit Trail Pop Up

Figure 60 - Audit Trail Previous Data Value



To return to the data entry screen select **Close**.

15.3 Audit Trail Report

All data changes logged under the Audit Trail function for a case can be listed in the Audit Trail Report.

This report can be selected from the Reports options. See How to select a report from the main screen and

Or by:

8. Selecting the Reports menu from the main screen
9. Then choose Select Report
10. The Select report screen will be displayed, see Figure 29 below.
11. Highlight the report name you wish to run and select  Run.

How to select a report from within a case. on page 45.

15.3.1 How to use Audit Trail Report Options

When the Audit Trail report has been selected the report option screen is displayed. See Figure 61 below.

The user has the following options:

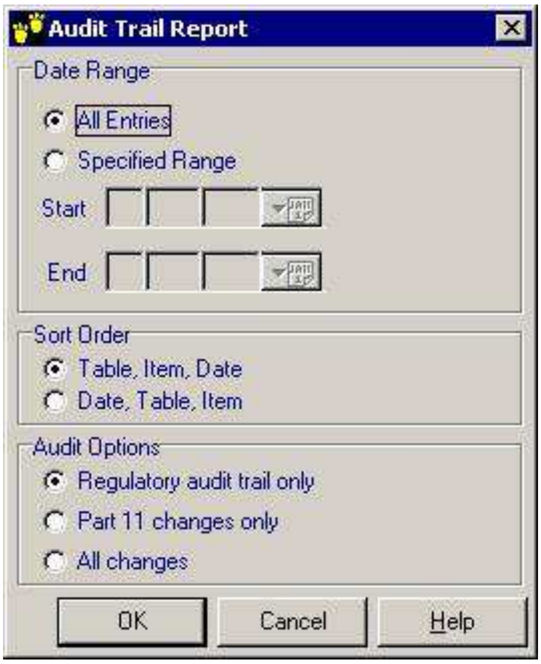
- Date Range — Either All Entries for the case ***or***
  Specified Range of dates - enter the start and end date of the changes you wish to report on.

- Sort Order — Specifies in which order the information is displayed on the report. Select Table, Item, Date, or Date, Table, Item.

  The 'Table Name' is the area of the database where the case information is stored The 'Item' is the field on screen that has been changed.

- Audit Options — These are included for releases of PV-Works prior to version 4 (or for users who have upgraded to version 4). It should be set to 'Regulatory audit trail only'.

Figure 61 - Audit Trail Report Options



5. An example of the audit trail report is shown below:

Case No : UK99VB10050

Audit Trail Report for All Entries

Table : CASE_ASSESS

Item	Old Value	New Value	Date	User	Reason
EXPECTED	False	True	15-Dec-1999 15:43:09	VTST_B1	New Data

Table : CASE_INFO

Item	Old Value	New Value	Date	User	Reason
AUDIT_ACTIVE	N	Y	01-Dec-1999 15:30:39	ALAN	Audit Trail Activated
AUDIT_ACTIVE	Y	N	01-Dec-1999 15:39:38	ALAN	Audit Trail Deactivated
SOURCE	Attending Veterinarian	Anti-poison centre	15-Dec-1999 15:02:47	VTST_B1	Incorrect Data
SOURCE	Anti-poison centre	Attending Veterinarian	15-Dec-1999 15:05:20	VTST_B1	New Data

NB: An alternative user audit trail has also been supplied by Assured in the form of a Crystal report – this is intended to provide a more user friendly method of reviewing audited data changes.

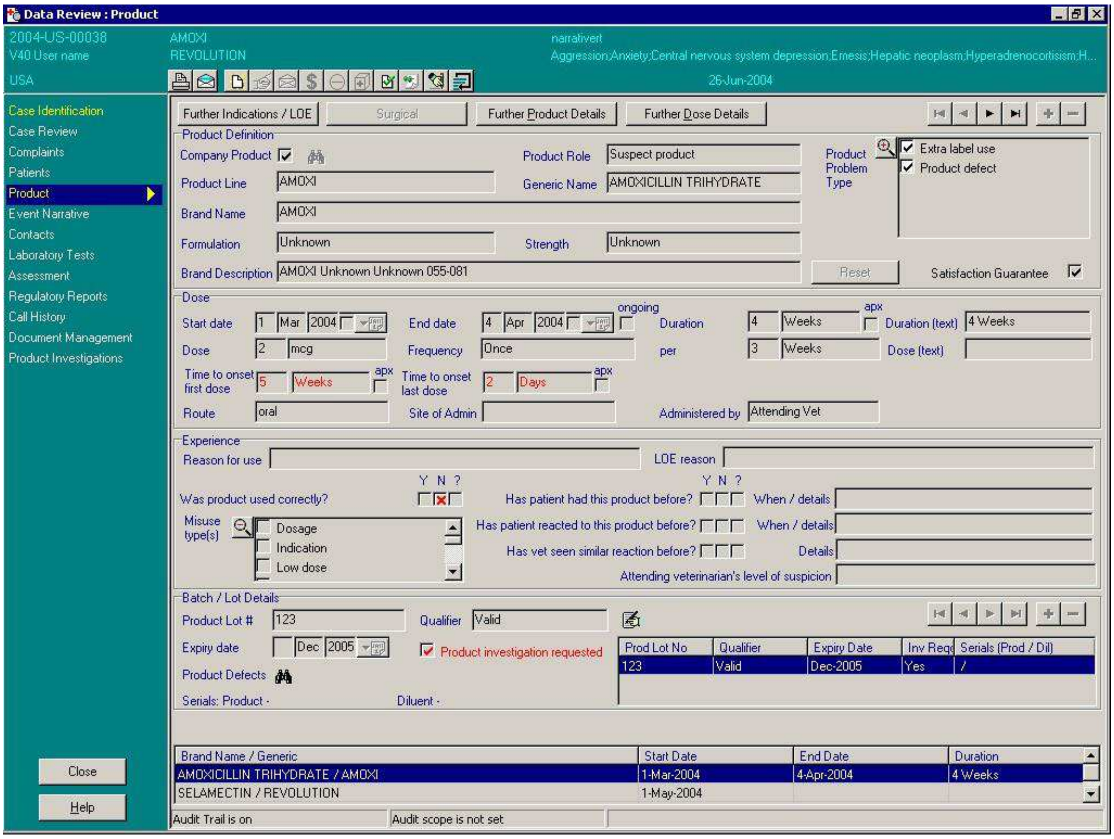
15.4 Data Review with Audit Trail

The Data Review with Audit Trail combines the functionality of Data Review function (see section 11) and Viewing the Audit Trail (see 17.2 Viewing the Audit Trail on page 76).

This option uses the Data Review screen format but highlights any field whose data has been changed, by displaying its current value in a red colour. The intention is to draw the user's immediate attention to those fields that have changed. The actual changes are displayed using the right mouse button (see 17.2 Viewing the Audit Trail on page 76).

In the example below the time to onset fields, 'was product used correctly' field and a request for an investigation have been edited under audit trail control and are displayed in red. All other data are presented in black text which indicates that they have not been edited since initial entry.

Figure 62 - Data Review with Audit Trail



15.4.1 How to Review your case with Audit Trail

1. From the main screen select **Data** and the **Review with Audit Trail** options.

2. All of the data entry screens are available to view, but the information without an Audit Trail is greyed out and the information with an Audit Trail is highlighted in Red. See Figure 62 above.

3. To view the Audit Trail field, select the field, select the right mouse and then View Audit Trail. (See 17.2 Viewing the Audit Trail on page 76)

4. The only options available are: Close Exit from Data Review mode ❑ Help Access the online help.

16 Help

16.1 PV-Works Help System

PV-Works (vet) contains an on-line help system. This follows the standard Windows help system functions. This provides:

- Contents List - for searching alphabetically through the help
- Index Search - for searching for help on key words or phrases
- In context help - where the help is linked to a function or screen within PV-Works.

16.1.1 How to access the online help from the main screen

1. You can access the online help contents by either

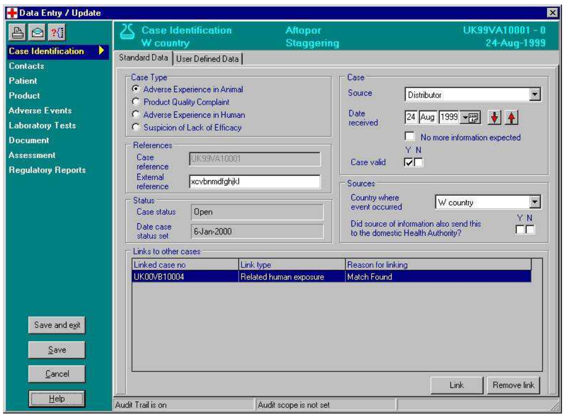
- Selecting from the main menu **Help** and the Help menu will appear
  Selecting **Contents** will take you to the online help contents screen.

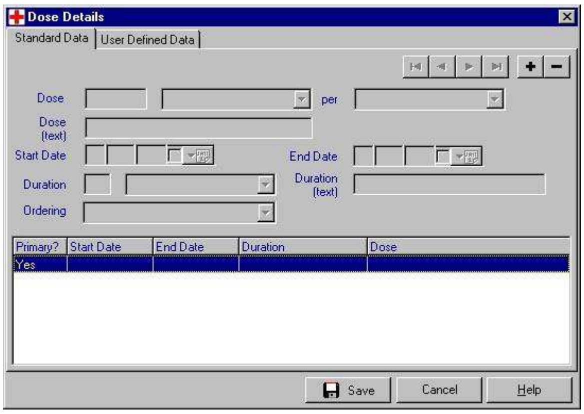
or

- Selecting from the main menu the Help Button. This will take you directly to the online help contents screen.

16.1.2 How to access the online help from the Data Update screens.

1. Calling the online help within the Data Update screens will link the user to the in context help for each screen.
2. You can access the help by selecting the Help button on the bottom of the screen or popups.





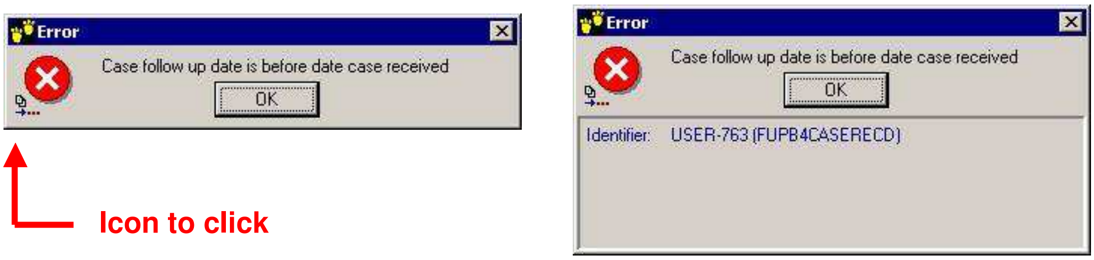
Help Button Help Button

16.2 Reporting Issues to Assured Information Systems Ltd

Your support staff and, in turn, Assured will appreciate a full description of any error you find. To help, please provide:

1. The case number generating the error
2. The function being used – eg update, CVMP report
3. Any error message – if PV-Works has provided an error message, click the icon in the left hand corner and record the error code, eg FUPB4CASERECD in the example in Figure 63

Figure 63 : Error Message



4. The name of the form. Form names can be displayed by clicking the ‘paws’ icon in the top left hand corner of the screen. This displays a small screen as in Figure 64.

Figure 64: Form Name Display