**Clincase Investigator User Guide (Web Client)**

**Quadratek**

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**Adapted by Institute of Medical Biometry and Informatics (IMBI)**

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# Clincase Investigator User Guide (Web Client), adapted version

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# Clincase - General Information

Welcome to the *Clincase Investigator's Guide for the Web Client*. This guide is intended to be read by personnel who will be using the browser-based web client in order to enter data into an electronic case record (eCRF) as part of a clinical trial. The guide may be used as a tutorial and is intended to be read "straight through" as an introduction on how to use the Clincase Web Client but it may also be used as a reference when you need to look up a specific topic.

## The Clincase Application

Clincase is a tool for remote data entry which supports the automated collection of electronic data (that is, it is an EDC or Electronic Data Collection system).

## Client Types

There are two different types of "client" program in Clincase: The "Rich Client" (which is Java-based and is also known as the "standalone client") and the "Web Client" (which is designed for use in a web browser and is also known as the "Ajax Client" because it uses Ajax, a group of web development technologies). ***This user guide describes how to use the Web Client*** - a different version of this guide is available for users of the Rich Client.

## Software Version

This user guide describes how to use the Clincase Web Client for release 2.5 of Clincase.

## Technical Requirements

In order to successfully run the Web Client, a minimum set of specifications must be met:

- Screen resolution of at least 1024x768
- Internet access with at least 768 KBit/sec (DSL)
- A web browser with:
    - JavaScript enabled
    - HTTPS enabled (default: HTTPS not blocked by a firewall)
    - The current list of supported browsers includes:
        - Internet Explorer (versions 6, 7 and 8)
        - Firefox (versions 2 and 3)
        - Safari


Should there be any questions regarding the browser or the equipment, the company's IT administrator should be contacted.

## Security Aspects

All data transmission is encrypted with secure socket layer (SSL) technology. The web server and the database server with the stored data are located in a secure data center and protected by a firewall. A backup is performed daily.

## Authorizations

All changes to data are logged with a computerized timestamp which includes the name of the author/editor, the date/time of the change, a reason for the change (if applicable) and the new information in an audit trail.

## Getting Started

In order to use the Clincase Web Client, you must have a valid user name and password, which should be obtained from your study coordinator. To get started, make sure that the computer is connected to the Internet and then start your web browser. Type the URL provided by your study coordinator into the browser's address bar - for example:

https://ccservXX/clincase/app

### Signing In

Once the URL has been found, a login screen appears (note that your screen may look different due to local customizations of the login page, but it will certainly include fields for the User Name and Password):



Fig. 1 - The Login Screen

Enter your assigned user name and password, then press the **Sign In** button. If your login attempt is unsuccessful, check that you have entered the correct values for the user name and password (and check that the **Caps Lock** on your keyboard isn't on) and try again. Upon your first successful login, you may be forced to change the password you were supplied to a new personal password. Whenever setting or changing your new password, be aware that your current password (and up to the last 10 passwords you may have used) may not be reused. If you have forgotten your password, click on the **Forgotten Password** link and follow the instructions on the displayed screens in order to receive a new system-generated password. Once you have successfully signed in, you will be redirected to the Clincase Home Page.

⚠️     It is essential that all passwords are kept secret.

## The Clincase Home Page

The Clincase home page provides an overview of the projects or "Studies" that can be accessed by the user, displays site-specific information for the user and provides links which allow the user to change their password and to sign out. It is made up of a header section, which displays information about the current user including the user's name and when they logged in and a main section, which includes a list of Studies the user can access (only if the user is participating in more than one Study) and a study-specific panel which provides information, buttons and quick links which allow the user to interact with the study.

## Multiple Studies Home Page

When the user is participating in more than one study, the Studies panel displays a list of all the Studies and allows the user to select which study to open.
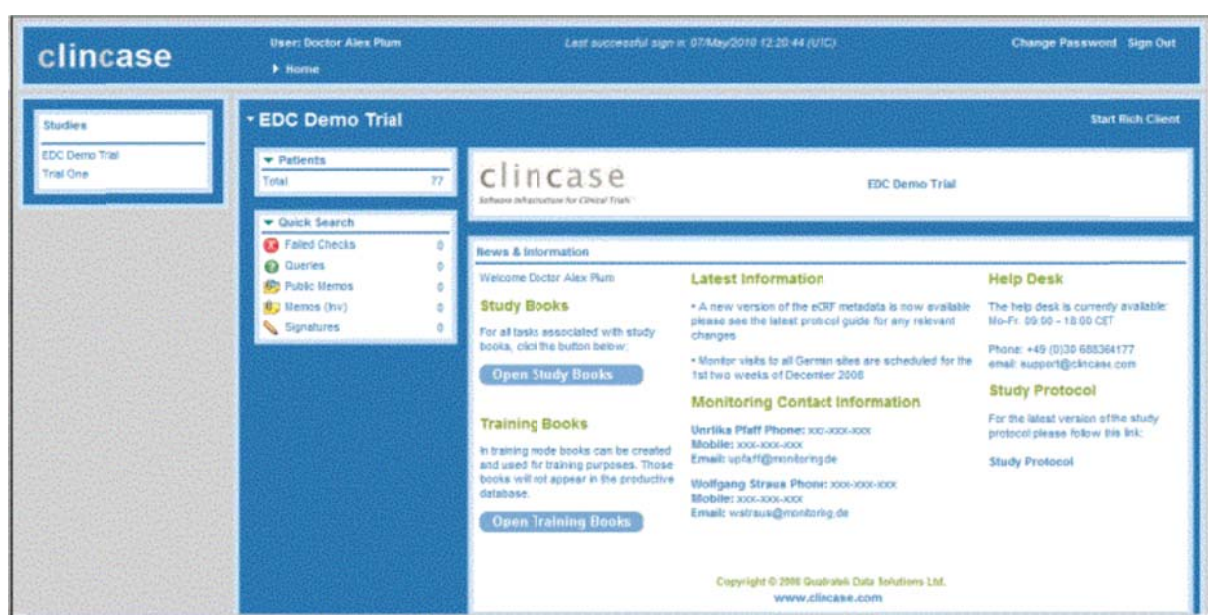


Fig. 2 - The Clincase Home Page - Multiple Studies

## Single Study Home Page

If the user is participating in only one study, the Studies panel is not displayed.
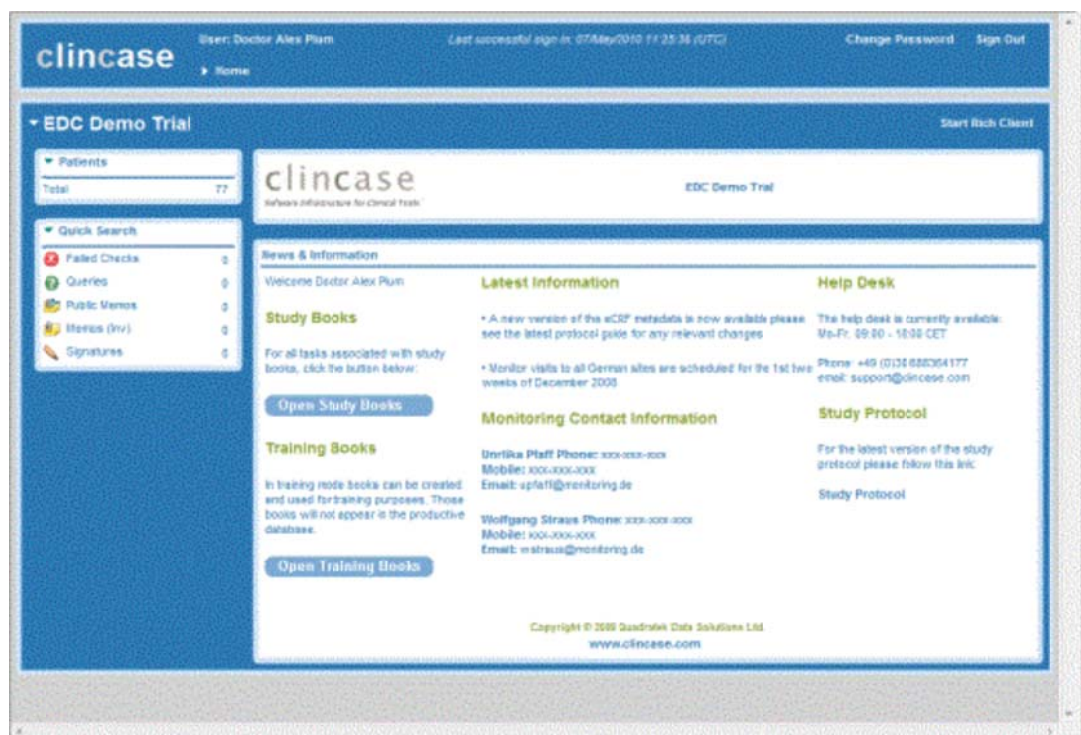


Fig. 3 - The Clincase Home Page - Single Study

## Current User

If the computer you are using is shared amongst colleagues, you must not forget to sign in with your own user account and sign out upon completion or when leaving the computer unattended. If the Clincase window is open, the currently signed-in user's name is displayed in the header section. Note also that the your current page's path is displayed at the bottom of the header section, in this case, it is simply "Home" because you have not yet opened a study book.



Fig. 4 - Current User's Details in the Header Section

## Opening the Study Books

In order to open the current set of Study Books for the Study, click the **Open Study Books** button (or th open the Training Books, click the **Open Training Books button).** The screen changes to display a toolbar, a list of current Study Books (or "Patients") and a set of panels on the left-hand side which display an Outline of where you are in the Study, the Quick Search panel and an Actions panel. To open a study book, simply click on the name of the study book from the list of books and you will be shown the first page in the selected study book.
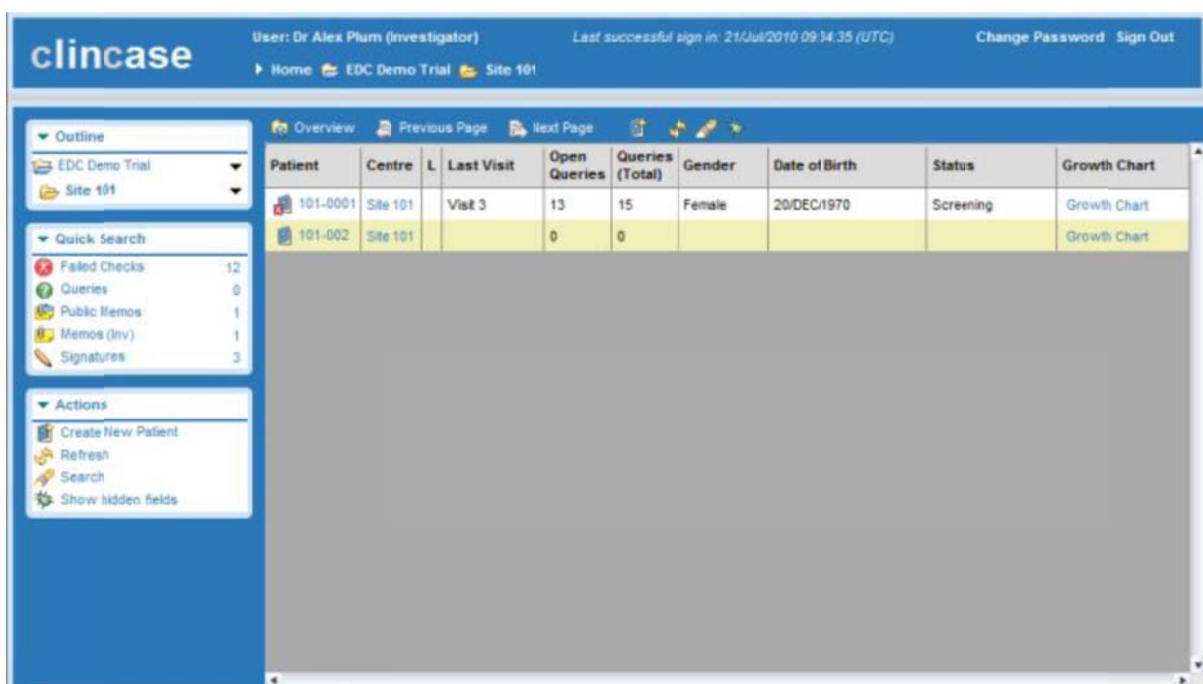


Fig. 5 - The Study Books Screen

## Using the Toolbar and the Panels

On the Study Books screen and most other screens you will be working with, you will see a toolbar at the top of the main section which provides two distinct sets of buttons: the first set of buttons allows you to navigate through the pages of the study and the second set allows you to perform actions such as to create a new study book (**Create New Patient)** or to generate a report (the **Search** button). The features offered by the buttons in the toolbar are mirrored by links in the **Outline** panel (links for navigation) and the **Actions** panel (links to perform actions). By the way, if you hover your mouse over a button, it will display a little popup window telling you what the button does.

## Creating a new Study Book

To create a new study book, (an eCRF for a new patient), click on the "create new patient" button in the toolbar or click on the **Create New Patient** link in the Actions panel.

You will be asked to confirm that you want to create a new Patient. Click on the **OK** button to continue.



A window opens. Depending on the study design, different study book template versions may be available.

Select the required version (by clicking on the appropriate row) and click on the **OK** button.
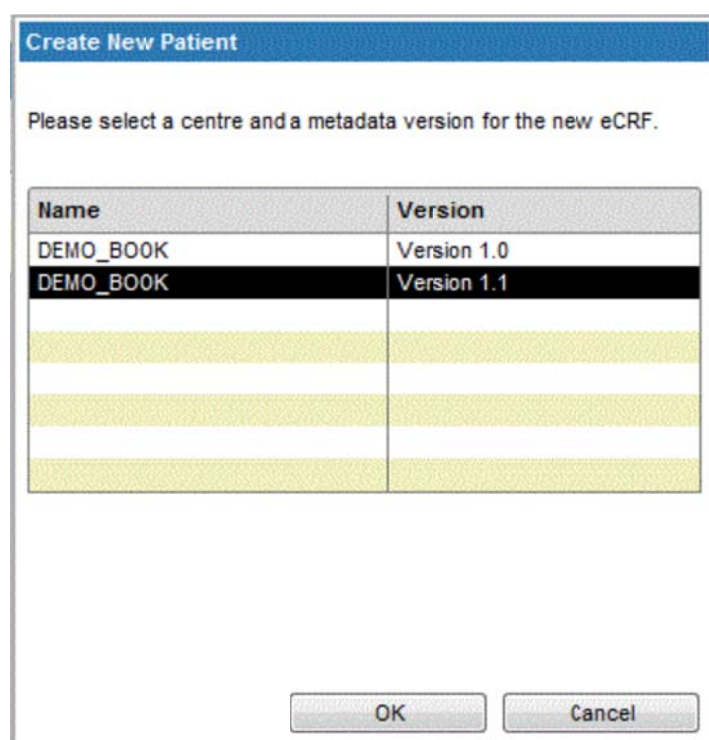


Fig. 6 - Create New Patient

After a few seconds, the first page of the new study book opens. The initial name of the study book (patient eCRF) is displayed at the top of the page; this book name depends on the study-specific design and may change after data has been entered. The new book is now open for data entry.


## Navigation

The term *navigation* refers to how you move between the pages which make up a study book. There are a number of ways to navigate through the pages of a book including:

- Clicking on the links on a page which link to other pages
- Clicking on the links displayed in the **Outline** panel
- Clicking on the links displayed at the bottom of the header panel
- Using the Up (Overview), Previous and Next Page buttons in the toolbar
- Clicking on a direct hyperlink on a page
- Using the "Go Back" and "Go Forwards" buttons of the browser itself
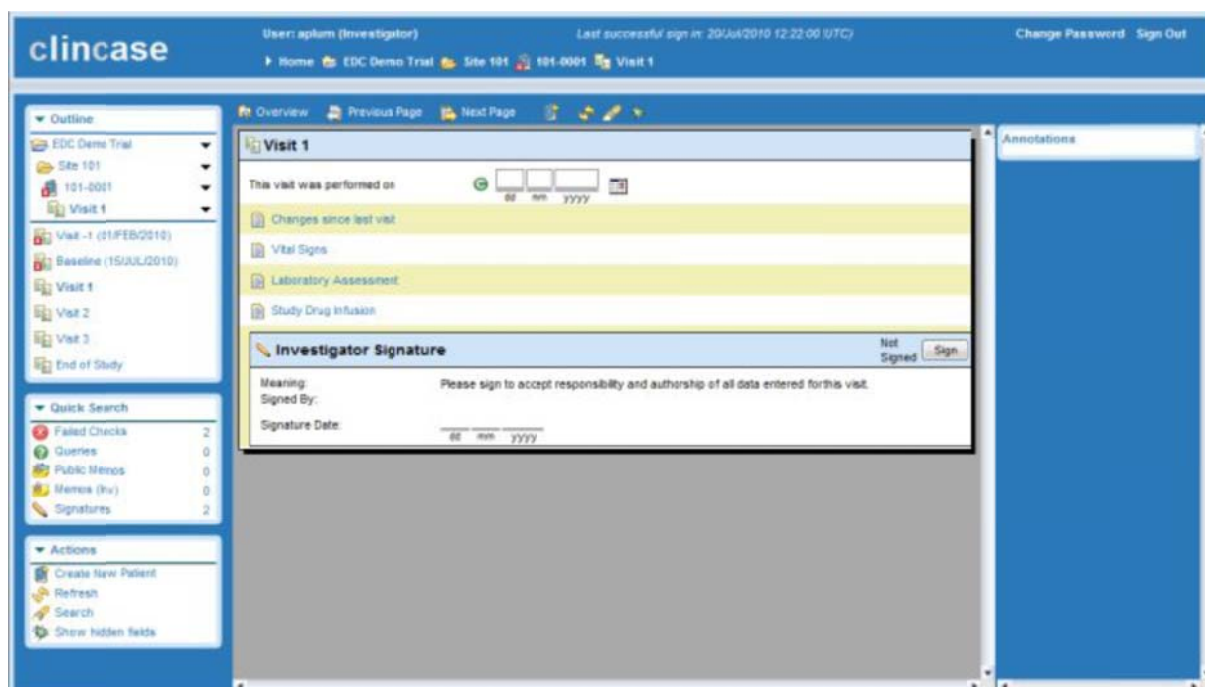


Fig. 7 - The Visit 1 Chapter page

## Links on a Page

The normal way to navigate through the pages of a study book is to click on a link to another page or section which is displayed on the current page. For example, take a look at the screen shot below of the Visit 1 Chapter page: *Changes since last visit*, *Vital Signs*, *Laboratory Assessment* and *Study Drug Infusion*. By simply clicking on one of these links, you will navigate to the selected page, for instance, by clicking on the *Vital Signs* link, you will navigate to the page where vital signs are entered. Note also the header section, where the "path" to the current page is displayed, in this case, the path is *Home -> EDC Demo Trial -> Site 101 -> 101-0001 -> Visit1.*

## Links in the Outline Panel

The **Outline** panel, on the upper left-hand side of the screen, contains a set of links for the current study book which can provide a quick and powerful way to navigate through the pages of a study book. The panel consists of two sections: an upper section which displays the hierarchical path from the top of the project down to the current page and a lower section, which displays the current page along with all of its "sibling" pages (those which also have links on the current page's parent page). For example, using the screen shot in Fig. 7 above, the top section displays links to *EDC Demo Trial*, *Site 101*, *101--0001* and *Visit 1* (which is highlighted in bold text because it's the current page) and

these represent the hierarchical "path" from the top-level project down to the current page. By clicking on any of these links, you will navigate directly to the linked page. If you look at the lower section, you will see the set of links (*Visit-1*, *Baseline*, **Visit 1** (in bold because it's the current page), *Visit 2, Visit 3* and *End of Study*) which include the current page and all of its siblings (that is, other pages linked to from parent of the current page). To illustrate that, here's the parent page of Visit 1:
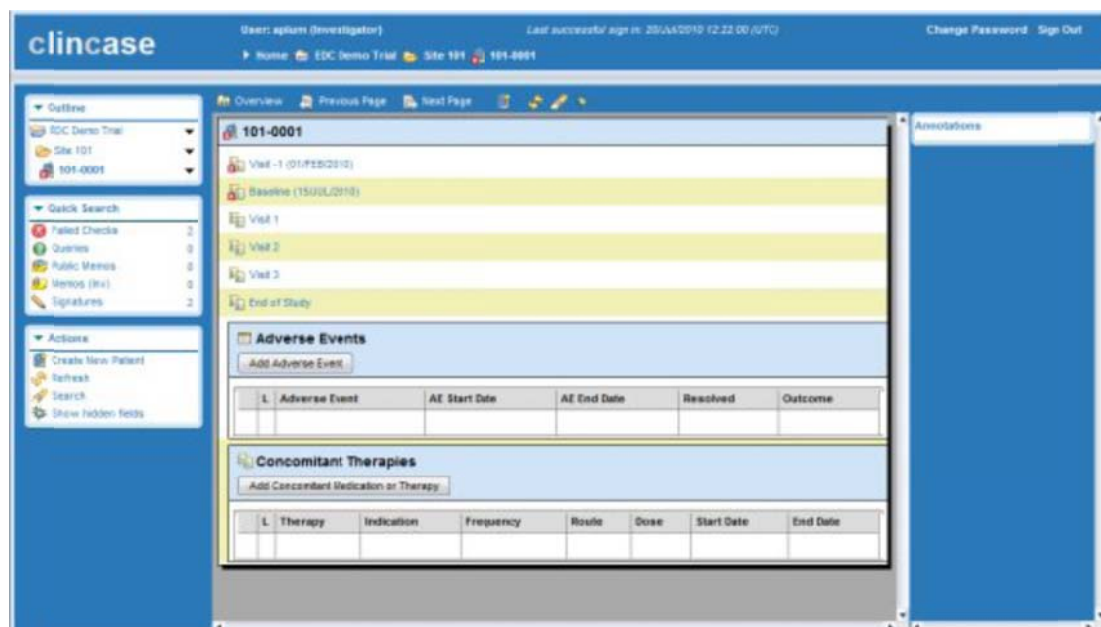


Fig. 8- The 101-0001 Study Book page

Notice that indeed, Visit 1 is in the middle of the other sibling links. Notice also that, because this is the study book itself, this page has no sibling pages and hence, the lower section of the **Outline** panel is not displayed by Clincase.

## Links in the Header Panel

The header panel displays your current "location" within a Study Book in a horizontal line of links representing the hierarchy of the current page. For example, in Fig. 7 above, the header panel displays links to *EDC Demo Trial*, *Site 101*, *101-0001* and *Visit 1* in a single horizontal line. By clicking on any of the items in the hierarchy, you can directly navigate to that page.

## Navigation Buttons in the Toolbar

The toolbar contains three buttons which can be used to navigate in three directions from the current page:

Up, Previous and Next:



Fig. 9 - The Up (Overview), Previous Page and Next Page Buttons

The *Up* button is very straightforward to understand and use but the *Previous* and *Next Page* buttons are a bit more subtle and their behavior depends on the document type of the current page.

## The "Up" (Overview) Button

The *Up (Overview)* button very simply navigates up one level in the hierarchy to the "parent" of the current page. So in Fig. 7 above, clicking on the up button from the current page (*Visit 1*) you will navigate up to its parent, which is the *101-0001* study book page.

## The "Previous Page" Button

The *Previous Page* button, if enabled, will navigate to the sibling page of the current page which is "previous" to or above the current page in the parent page if there is such a sibling page, otherwise it will navigate to the parent page of the current page (like the Up button). For example, look at the following screen shot:

Fig. 10 - The Vital Signs Page

By clicking on the *Previous Page* button you will navigate to the *Changes since last visit* page because it is the sibling of the current page which is directly "above" it on the parent page (you can see that this is the case if you look at the lower section of the **Outline** panel). Then, if you click on the *Previous Page* button again from that page, you will navigate to the *Visit 3* chapter because the current page has no sibling above it and therefore it will navigate to its parent, the *Visit 3* chapter.

## The "Next Page" Button

The *Next Page* button, if enabled, will *either* navigate to the next page of the current chapter *or* to the next sibling page of the current one (the one <u>below</u> it), if there is one. For example, if the *Next* Page button is pressed in the page displayed in Fig. 10 above, the *Laboratory Assessment* page will be displayed. If however, the current page being displayed is a chapter, then clicking the *Next Page* button will display the first page in that chapter. For example, in Fig. 7 above, clicking the *Next Page* button will navigate to the *Changes since last visit Visit 1* is a chapter.

## Hyperlinks

Hyperlinks can be found on some pages and can be used as shortcuts to other forms (shown below). By clicking on a hyperlink, the application navigates to the specified page. In doing so, forms may be skipped and will not follow the usual sequential page order.

Fig. 11 - A direct hyperlink

⚠️ By using hyperlinks, forms may be skipped. Upon completing a visit, please ensure that all required fields have been populated by checking the visit completion status flag (completion status is discussed in the *Filling in Forms* section of this user guide).

## Browser Forward/Backward Buttons

The *Forward* and *Backward* buttons in your browser may be available for navigation and will utilize the normal history-based breadcrumb trail to navigate through the pages of the study you have previously visited.

# Filling in a Form

The Clincase Web Client provides a straightforward user interface which simplifies the entering of form data; users accustomed to other applications and websites should find it easy to use. Forms contain various types of fields which allow the user to enter data, select from a set of options, click on checkboxes and so on.

## Saving Data

The Clincase Web Client automatically saves the user's input - this means that data which has been entered onto a form does *not* need to be explicitly saved as with most web applications that require clicking a **Save** or **Submit** button. On leaving a field, entered data is submitted and saved automatically.

ℹ️ If there are any questions regarding the study protocol or regarding the information to be filled in, please contact the Monitor/CRA.

If there any technical questions, please consult this manual or contact support.

## Field Status

Each data entry field is marked with an icon which indicates its *status*. A field which has not had data entered into it yet is marked as "incomplete" or "missing data". Once it has had data entered into it, it is considered "complete" or "populated". Sometimes, a field is not available for data entry and such a field is called "disabled". As you can see below, data items that are incomplete are marked with a red flag with an "X" which is superimposed on the icon of the item. Once the field is populated, the flag's color changes to green with a "√". Disabled fields are "grayed out" and do not allow data entry; such fields are typically disabled and/or (re-)enabled by "Constraints" (discussed below). Note that upon entry to a page for the first time, as soon as the first field is supplied with data, all the other fields on the page will display an incomplete icon and will remain in that state until they are supplied with data or marked as "Not Available" (see "Not Available" below).

| Missing Data | Populated Data | Disabled Field ("Stop Date") |
|---|---|---|
| Date of Visit 1    [ ] [ ] [ ] <br> dd mm yyyy | Date of Visit 1    [10] [06] [2007] <br> dd mm yyyy | Ongoing at study end   ○ no ○ yes <br><br> Stop Date   [ ] [ ] [ ] <br> dd mm yyyy |

Fig. 12 - Field Status Icons

## Constraints

In many cases, a form will be set up so that some fields may or may not need to be completed, e.g. fields concerning a pregnancy test would not need to be completed if the patient were male, or the Stop Date of an ongoing event would not need to be completed until/unless the event had ended (was no longer ongoing). In such cases, these fields are usually disabled (see previous section) until/unless other fields are set in such a way to indicate that the disabled fields should be enabled. In the example below, the "Stop date" field, which was previously disabled, becomes enabled when the user selects "No" for the "Ongoing at timepoint of visit1?" field.

| | |
|---|---|
| Onset | [14] [04] [2010] <br> dd mm yyyy |
| ■ Ongoing at timepoint of visit1? | ○ Yes ● No |
| ■ ■ Stop date | [ ] [ ] [ ] <br> dd mm yyyy |

Fig. 13 – Constraints

## Not Available

On some forms, if a value is not available/not known/not applicable/etc., the field may be completed by setting a "Not Available" flag on the field. To set this flag, click the mouse button on the status icon of the data item concerned. A context menu opens and the "Not Available" flag from the submenu may be selected (see below).
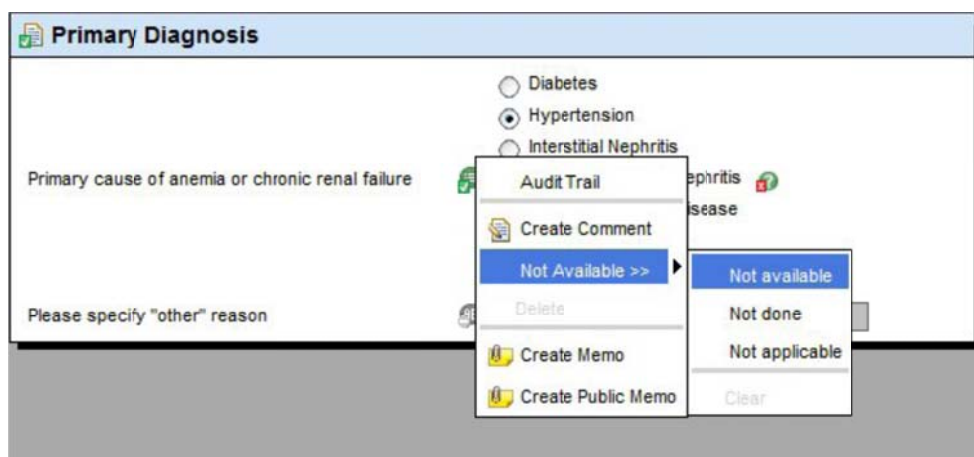


Fig. 14 - "Not Available" Menu

If a field has been marked as "Not Available", the status flag changes. The "Not Available" flag is shown in the screen shot below - it is indicated by the appearance of an exclamation point in a yellow triangle.
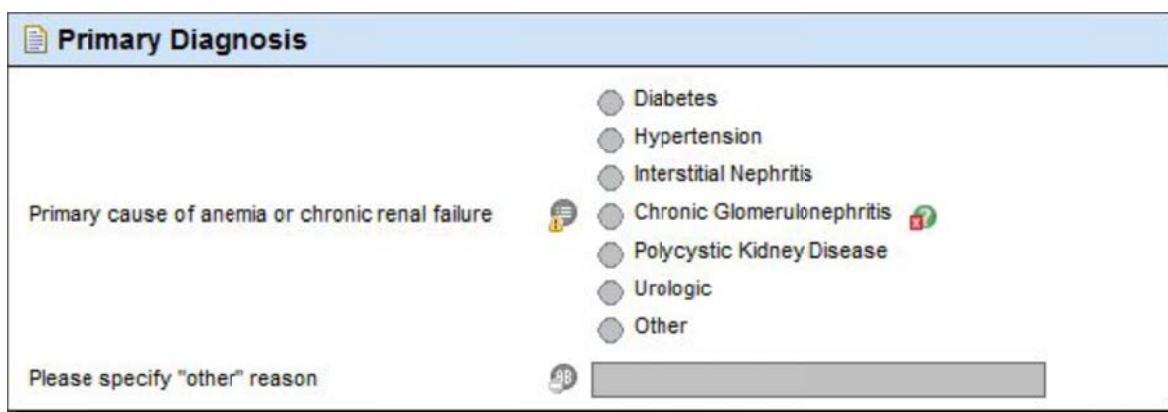


Fig. 15 - "Not Available" Status Flag

To remove the "Not Available" flag, open the context menu again and select "Clear".

⚠ The "Not Available" menu is disabled for mandatory items. These fields *must* be filled in. In the event of it being impossible to provide the requested information, please contact the Monitor/CRA or support.

ⓘ Depending on the study design, the "Not Available" option is also available for a whole item/section/page/visit. Click on the icon of the level concerned and proceed as described above.

## Queries

Clincase provides mechanisms to facilitate the exchange of information between Investigators and Monitors via Queries. Queries are used in Clincase to raise and resolve questions between the Monitor and an Investigator and to act as reminders to the Investigator.

- a *Query* is a question raised by a Monitor to request information or clarification from an Investigator. It is answered or resolved when the Investigator replies to it.

⚠ Queries are features which may or may not be visible to a user based upon the study design and the user's rights and roles.

## Resolving a Query

A *Query* is raised by the Monitor when he/she sees something that has been entered in the eCRF which requires clarification or explanation by the Investigator. Once raised by the Monitor, the Investigator needs to respond to the query ("resolve the query").

A Query from the Monitor appears on a form via the green question mark icon with a red "X" square in its lower left-hand corner. In addition, the Query is displayed in the **Annotation** panel:



Fig. 30 - An Open Query

To respond to a query, click on the query icon and select the **Answer...** option:



Fig. 31 - Responding to a Query

Enter your reply into the **Answer... Query (Open)** window and press the **OK** button:



Fig. 32- Entering the Query response text

Once answered, the query icon changes to display a yellow arrow pointing to the left to indicate that the query has been resolved and will be dealt with by the Monitor. The Annotations panel also shows that the query has been answered:



Fig. 33 - A resolved Query

# Dynamic Forms

Some forms can be created dynamically, as and when required, e.g. medications, adverse events, etc.

Dynamic forms are presented as a section on the page with a title, an **Add** button and a table listing those dynamic forms which have already been created (see Fig. 34 below).



Fig. 34 - A Dynamic Form

The content of the overview's columns depends on the study design and pages containing missing data are flagged accordingly (see item 2 in the example).

To create a new form, click on the appropriate **Add** button (**Add Concomitant Medication or Therapy** in our example). A new empty form of that type opens (see Fig. 35 below). Upon completion of the new form, click on the **Up** button ( ) to return to the page containing the overview. The new form is now listed in the overview.

Fig. 35 - An Empty Dynamic Form Entry Page

To open a previously-created dynamic form, click on its Index link in the table listing the dynamic forms. Note that the dynamic form will typically have a name which indicates its origin (see Fig. 36 below).

Fig. 36 - A Completed Dynamic Form

To modify or delete a previously-created dynamic form, open the form, then click on the icon of the page to bring up the context menu and select **Delete** from the context menu. Confirm the action when the confirmation dialog opens automatically. The list of dynamic forms will now display the deleted form as deleted (it will be grayed-out and marked with a deleted icon).
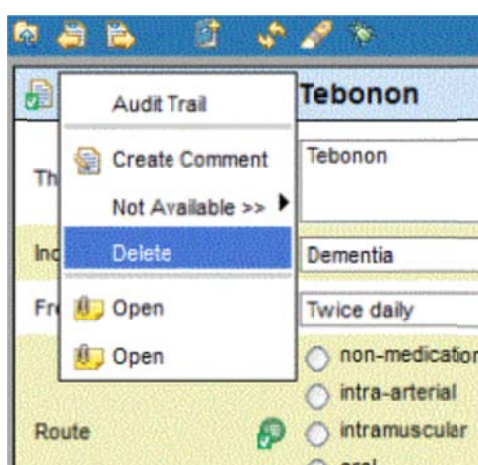


Fig. 37 - Deleting a Dynamic Form

To restore a deleted page, open the context menu again and select **Restore**.

## Linking Dynamic Forms

Often in an eCRF, one type of dynamic form is linked to another. For example, it is often desirable to link the medication prescribed to deal with an adverse event (generally known as the "concomitant medication"), as in the example below (Fig. 38) which shows a link field from an Adverse Event entry form which is used to link to the concomitant medication administered for the AE:
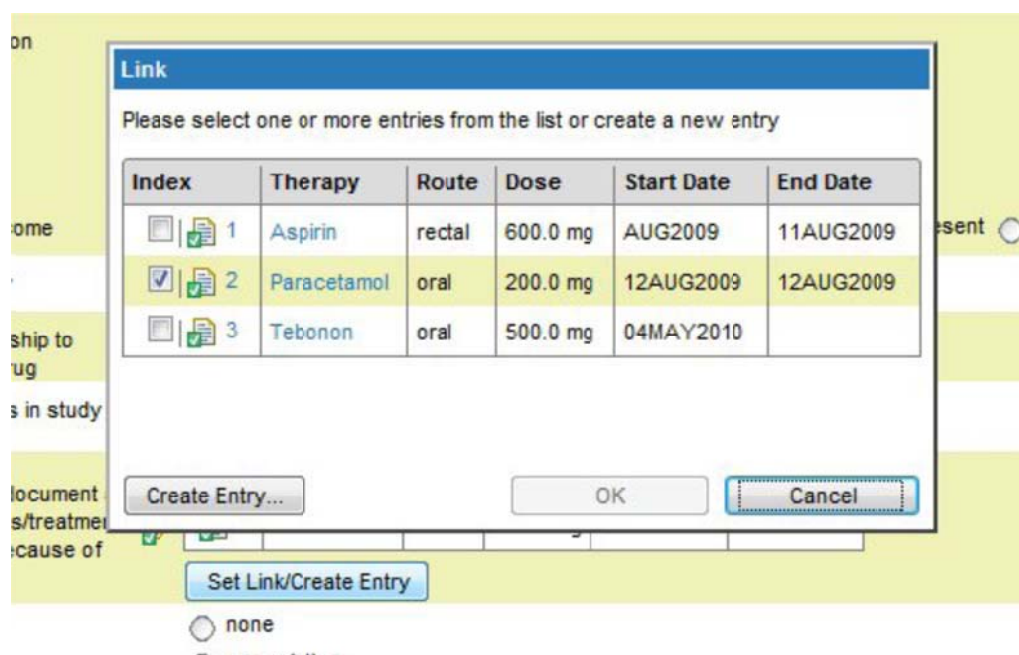


Fig. 38 - Links between Dynamic Forms

When the **Set Link/Create Entry** button is pressed, a window displaying the table of the current set of target dynamic forms is displayed:



Fig. 39 - Links Display Window

The user can then select one or more existing rows to link to (by clicking on each item's checkbox) or can instead press the **Create Entry...** button to dynamically create a new entry and link to it. When a link has been created to another dynamic form, the header section of the linked-to form displays a link back to the linking form:

Fig. 40 - Linked Form showing links from

## Checks

Depending on the study design, the eCRF may contain automated "checks", which test the validity of entered data. If a check detects implausible data, the check "fails". Failed checks are indicated with an icon showing a red disk with a white "X" and are also displayed in the **Annotations** panel, both of which can be seen in Fig. 41 below.



Fig. 41 - A Failed Check

⚠ Checks are governed by a workflow created by the system administrator, therefore this section describes the *default* behavior of Clincase.

### Soft Checks

Some values might be implausible, but not impossible. In this case, the failed check can be "accepted" (see Fig. 42). Notice that a Soft Check icon has a little "A" superimposed in the lower left-hand corner of the failed check icon. If this option is selected, the user is prompted to enter further information to explain or justify the data. After accepting the check, the flag is struck through to indicate that the check has been seen and that the information given confirmed (see Fig. 44 below).
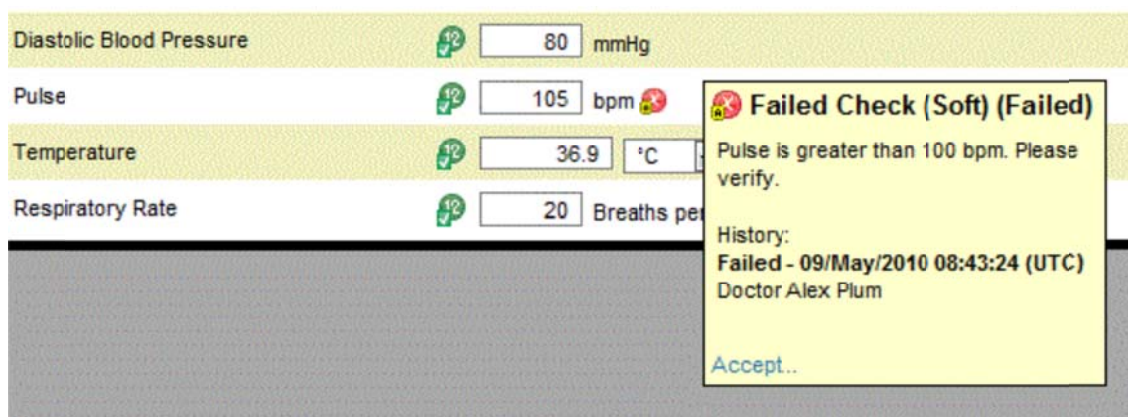
Fig. 42 - Accepting a Soft Check



Fig. 43 - Prompting for an explanation when accepting a Soft Failed Check
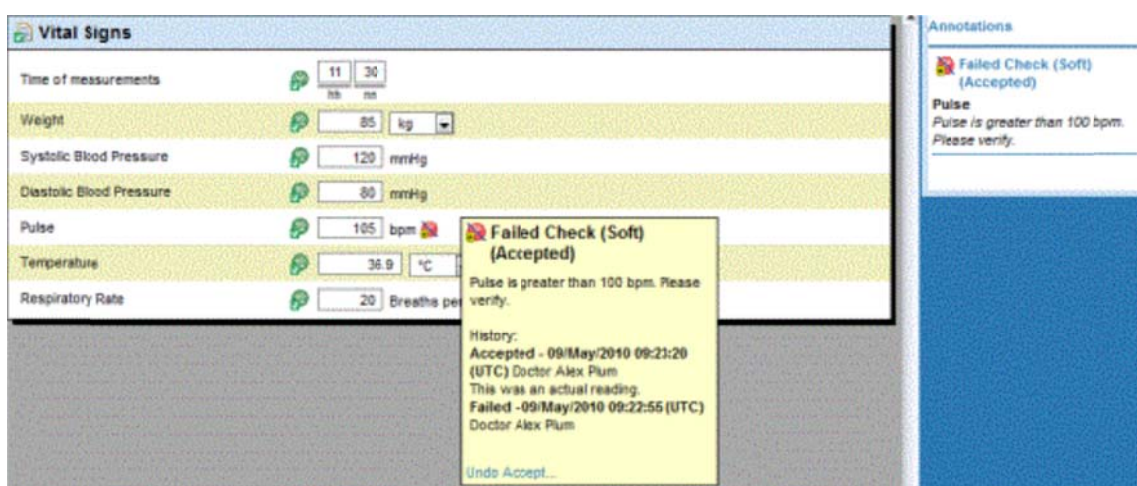


Fig.

44 - Soft Failed Check is Accepted

ⓘ Depending on the study design, soft checks can be used as "reminders", e.g. if an exclusion criterion is met.

ⓘ To avoid queries from the Monitor/CRA, try to provide an explanation to explain the correctness of the information given (if appropriate) when prompted.

## Hard checks

If data is obviously implausible, the check is a "hard check". Such checks cannot be "accepted" (see Fig.45 below - note the absence of the **Accept** option and of the little "A" on the icon). The check flag only disappears when data is corrected. However, if there really is a plausible explanation for entered data, please contact the Monitor/CRA or support.



Fig. 45 - Hard Check Failed

ⓘ To find queries and failed checks, use the "Search" or the "Quick Search" function (see the "Quick Search" section elsewhere in this guide).

# Signature Field

In a typical study, upon completion of the forms of a visit, the visit usually needs to be signed (see Fig. 46 below). The Signature Field header displays the current state of the signature ("Not Signed" in this example) and has a **Sign** button. In the body of the signature, a "meaning" (which indicates what the user is agreeing to or acknowledging with the signature) is displayed along with the details of the signature itself (in Fig. 46 below, the "meaning" is "Please sign to accept responsibility and authorship of all data entered for this visit.").
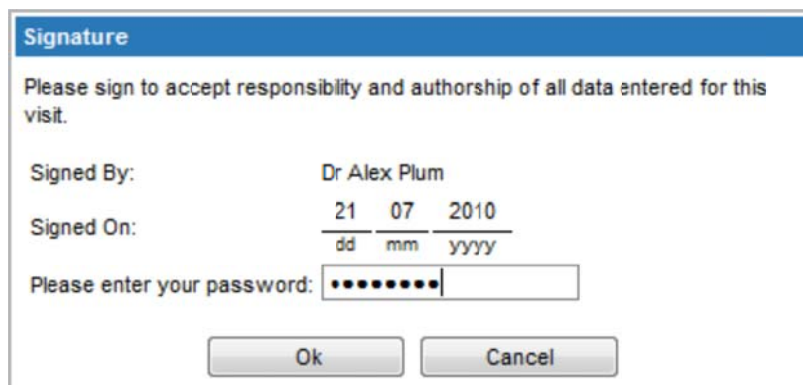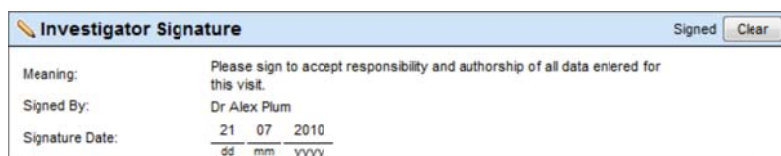


Fig. 46 – Unsigned Signature

To sign the Signature, click on the Sign button. A window opens in which the user's password must be entered. By entering their password, the user "signs" the signature and the "meaning" stated within the signature is confirmed.



Fig. 47 - Signing the Signature

Once the signature has been signed, the status in the header changes to "Signed" and the **Sign** button becomes a **Clear** button. Pressing the **Clear** button "clears" the signature, returning it to the "Outstanding" state.



Fig. 48 - A Signed Signature

## Outline Panel

The outline panel provides a mechanism for quick navigation through the eCRF, (see Fig. 49 below). The panel consists of two sections, each of which provides direct links to other pages in the study:

- Hierarchical Display: the upper section of the panel displays the hierarchy of the current page, starting from the project and continuing down to the current page
- Siblings and Dynamic Pages: the lower section of the panel displays the set of sibling pages of the current page (with the current page displayed in bold text) and it also displays dynamic pages of the study book

By clicking on any of the links shown in the panel, the user can quickly navigate to the selected page.
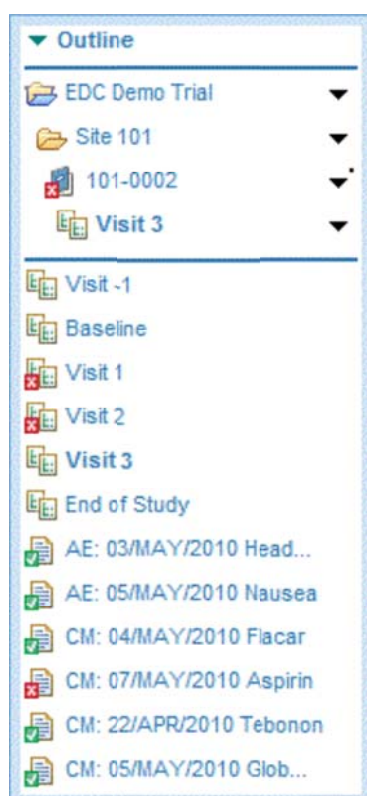


Fig. 49 - The Outline Panel

# Quick Search

The Quick Search panel presents the user with a summary of Failed Checks, Queries and Signatures either for an individual study book (patient) or for an entire site. The links in the panel provide the ability to quickly search for and navigate to any of these items (see Fig. 50 below). In addition, the panel displays a count of the number of items against each of the links which will be found by the search.

⚠ The specific content of the Quick Search Panel (the actual types and counts listed) depends on the user's rights and on the study design, so your Quick Search Panel may not look like the example below.

🛈 If the study books overview list is open, the quick search will show open "issues" for all of the study books. When in a specific study book, the quick search results contain all open "issues" of this single study book.
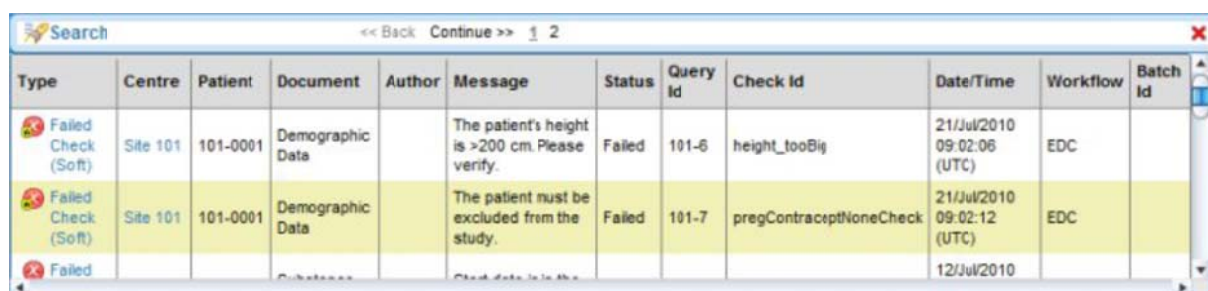
🛈 To search through a large set of items, use the full **Search** facility (see the "Searching and Reporting" section later in this guide for details).



Fig. 50 - The Quick Search Panel

## Quick search results

By clicking on one of the Quick Search items (in the example below, the **Failed Checks** item), the **Search** results table opens at the bottom of the screen, as shown below.



Fig. 51 - Search Results for Failed Checks Quick Search

1. Click on the link of the desired result row to open the eCRF form concerned. The page containing the selected item (Failed Checks in this case) opens automatically and the details of the item are displayed.

2. The number of items displayed in the results window is limited. Use the scroll bar on the right-hand side to scroll up and down the table.

3. When the number of results is large, multiple pages will be returned. Use the **<<Back** and **Continue>>** links or the page number links, all of which are displayed in the header of the **Search** table.

4. To close the **Search** window, click on the cross in the top right-hand corner of the table.

## Actions Panel

The Actions Panel, shown below, contains links to provide quick access to several actions. These actions are also available via buttons in the toolbar:
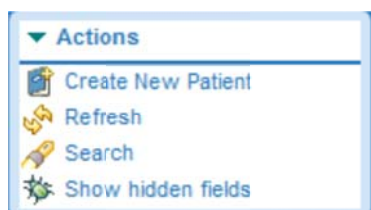


Fig. 52 - The Actions Panel

⚠The specific content of the Actions Panel (the Actions listed) depends on the user's rights and on the study design, so your Actions Panel may not look like the example above.

The available Actions are:

1. **Create New Patient** - used to create a new study book or patient (see "Creating a New Study Book" elsewhere in this guide).

2. **Refresh** - refreshes the current screen, which might make available new versions of books to use when creating a new study book.

3. **Search** - opens the **Search/Reports** window, which can be used to search and to generate reports (see "Searching and Reporting" elsewhere in this guide).

4. **Show/Hide hidden fields** - instructs Clincase to display or to hide fields which are normally hidden on forms (the label toggles between **Show** and **Hide**).

## Changing Data

All changes to data/information on a paper CRF have to be traceable. Every data change has to be dated, signed and the correction/modification of the data explained. Clincase tracks the changes automatically, as described in this section.

### Reason For Change

If data/information in the eCRF is changed, Clincase typically asks for a *Reason For Change* or *RFC*. When the user moves away from the field which has just been changed, the Reason For Change dialog may be displayed. Note that the Reason For Change will only be requested if the data has actually changed since the page was visited, so no Reason For Change is requested when the data is entered into a field for the first time, or when the change to the data is made before the page is navigated away from. The user may then either select from one of the "standard reasons" displayed in a scrollable window or may instead enter a custom reason as free text in the text window provided at the bottom of the dialog window (by clicking on one of the "standard reasons", the text for that selection will populate the text window). Once the RFC has been entered into the text window, press the **OK** button to close the window and complete the change. By clicking on the **Cancel** button, the change to the data item is undone.
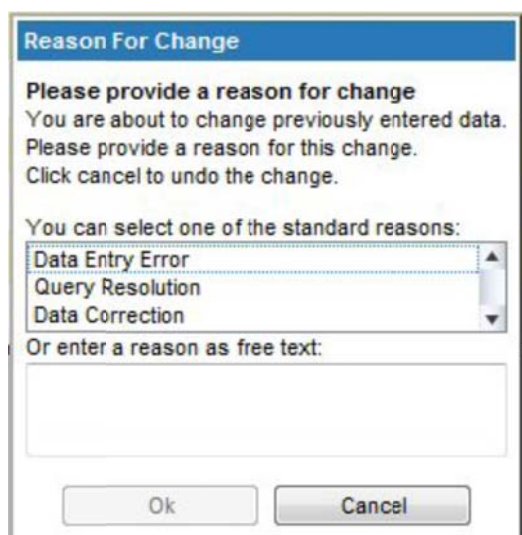
Fig. 53 - The Reason For Change Window

## The Audit Trail

The original entry to and all subsequent changes to any data item are automatically logged in an Audit Trail, which represents a complete history of the data entry operations of a field. The Audit Trail contains one entry for each data operation on the field which contains a computerized time stamp, the name of the user making the change, the path of the form, the label of the field concerned, the action performed, the new value, and the Reason For Change (RFC). See Fig. 55 below.

The audit trail can be viewed from the context menu of a single item, section, page, visit, or of a complete study book.
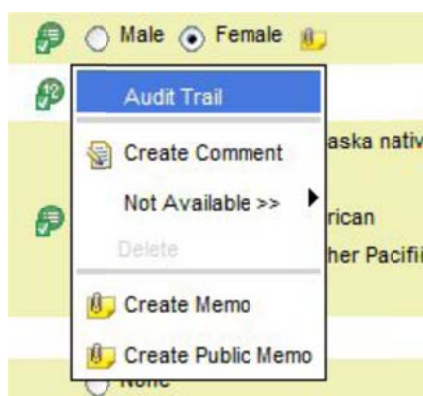


Fig. 54 - Selecting the Audit Trail option from the Context Menu

The entries in the Audit Trail are listed in oldest-to-newest order starting with the audit of the original data entry. Press the **Close** button to dismiss the window.

Fig. 55 - The Audit Trail for a page

# Searching and Reporting

Clincase provides a **Search** facility which allows the Investigator to perform searches, produce reports and export data from the eCRF. The user can select from a number of different "standard" searches and can usually select the format of the search output, which can be a table on the screen, a PDF file which can be downloaded or an Excel spreadsheet which can also be downloaded. Note that the set of searches/reports which are available to a user are configurable by the study designer, so you may not see all of the search options on your screen which are show in the figures below. Please see the *Manual* for further details.

## Starting a Search

To begin a search/generate a report, either click on the search button  in the toolbar or click on the **Search** action in the **Actions Panel**. Either action will open the **Reports/Search** window (see Fig. 56 below). The upper section is the **Reports** area, while the lower section displays the table of **Search** results. The **Reports** area is further divided into the **Reports** selection window on the left and the **Report Properties** window on the right.
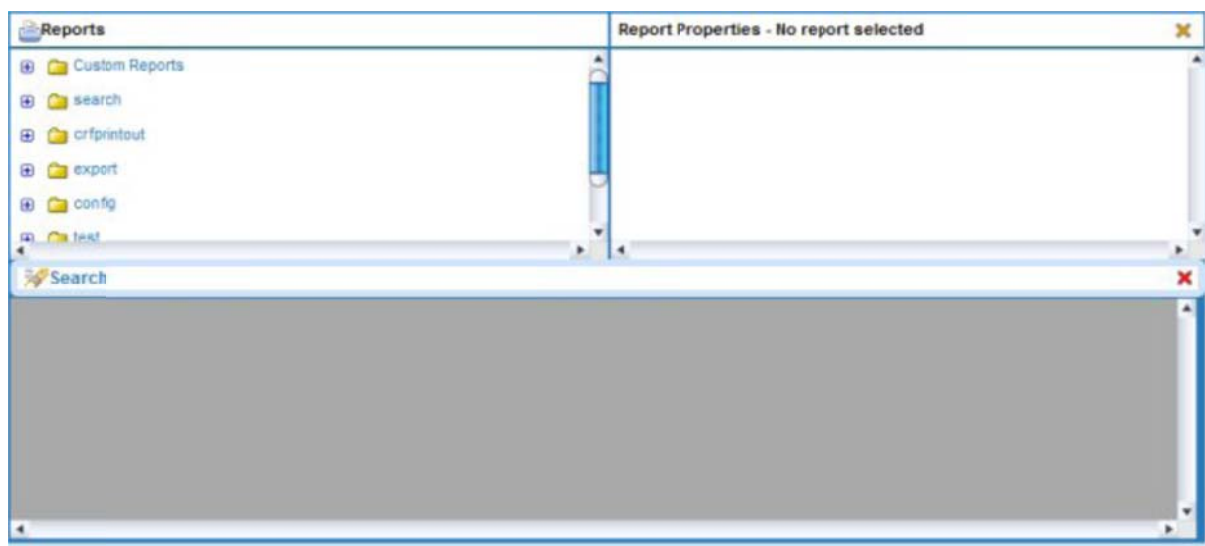
Fig. 56

## Selecting the Search/Report

In the Reports window you will see a tree-list of report groups, each of which contains individual search/report types. Click on the ⊞ button to expand the group and display the individual items. For example, see Fig. 57 below, where the "Custom Reports" group has been expanded.
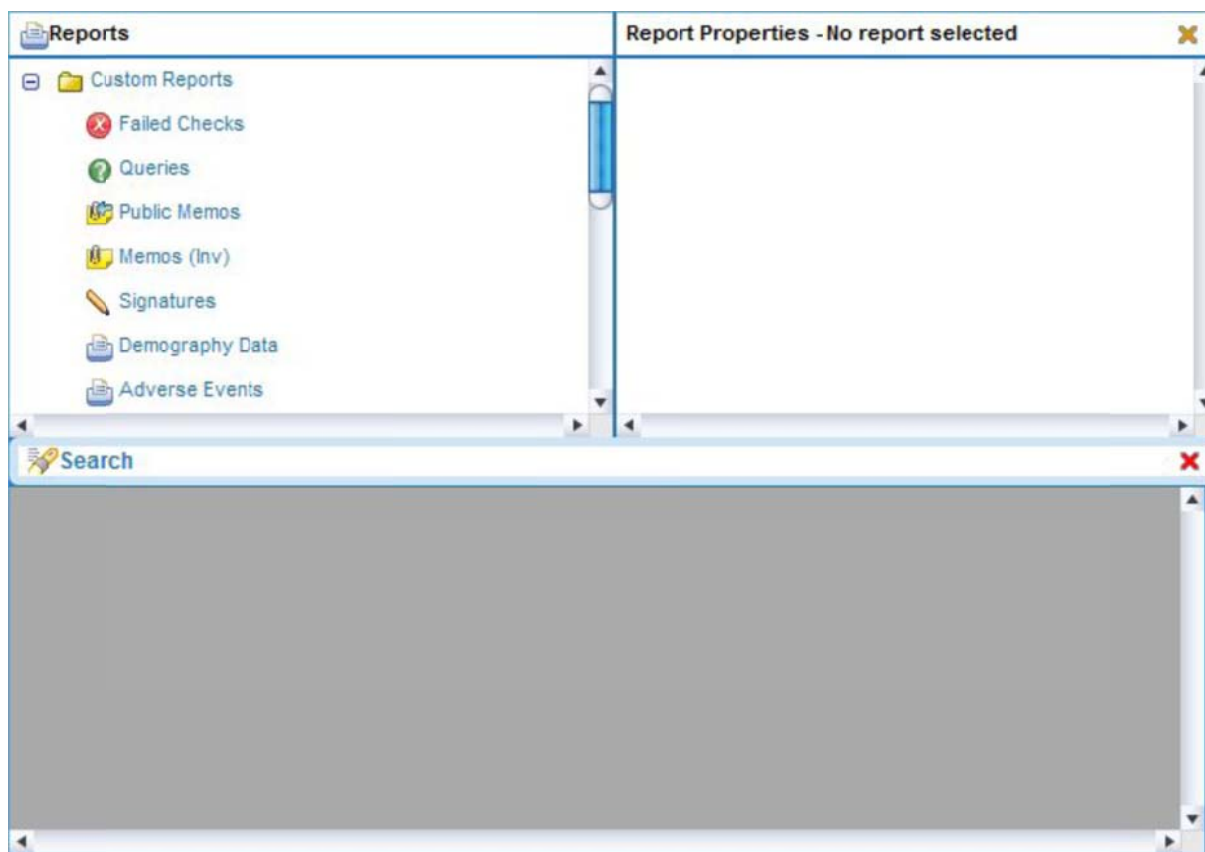


Fig. 57 - Expanding the Custom Reports Group

## Specifying the Search/Report Properties

Click on a search/report item from the expanded group to perform a search. The **Report Properties** window will be initialized with the default search/report options for the selected search/report and the **Search** table will display (some of) the results of the search (see Fig. 58 below for an example of the Audit Trail report from the search group). Notice that in the **Report Properties** window, you may select the format of the output (the Target), and most reports will provide other filtering options which can be used to refine the search as required. After selecting options from the window, click once again on the required Target to re-generate the report.
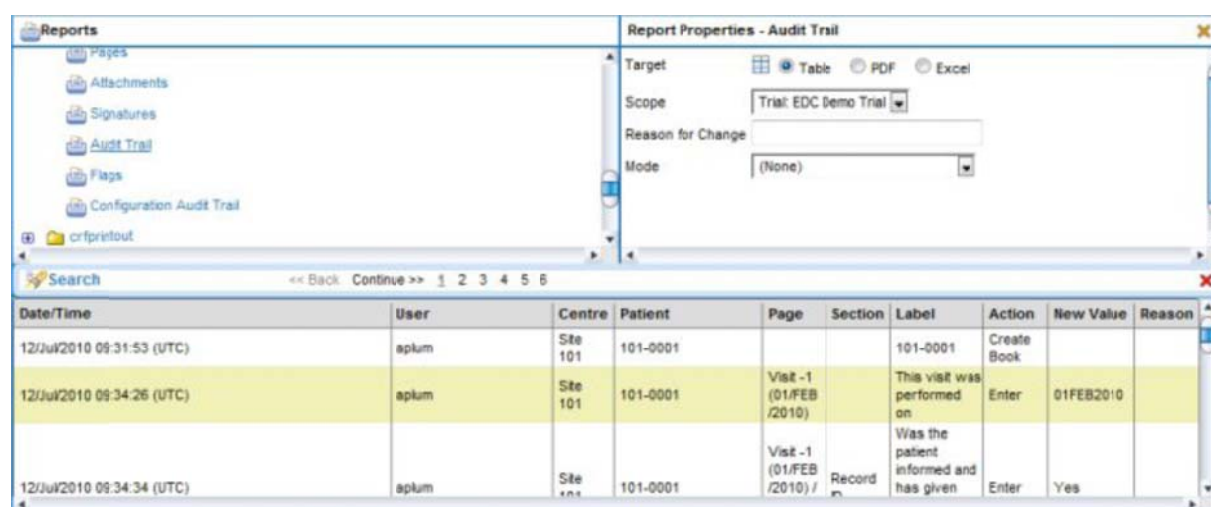


Fig. 58- An example of the Audit Trail report

## Generating PDF Files and Excel Spreadsheets

Once the search/report has been selected and the search performed, the user may change the settings in the **Report Properties** window in order to filter the results and/or to generate either a PDF file or an Excel spreadsheet, both of which can be downloaded to the user's system via a convenient hyperlink. The top row of the **Report Properties** window displays the **Target** option, which defaults to Table but which (for most reports) may offer the option to generate PDF or Excel output. Once the target type is selected, Clincase generates output in the selected format and, in the case of PDF or Excel, displays a link (labeled "Click to download file") in the **Search** results window which can be clicked to download the resulting document and which will typically start up the appropriate application to display the downloaded file.
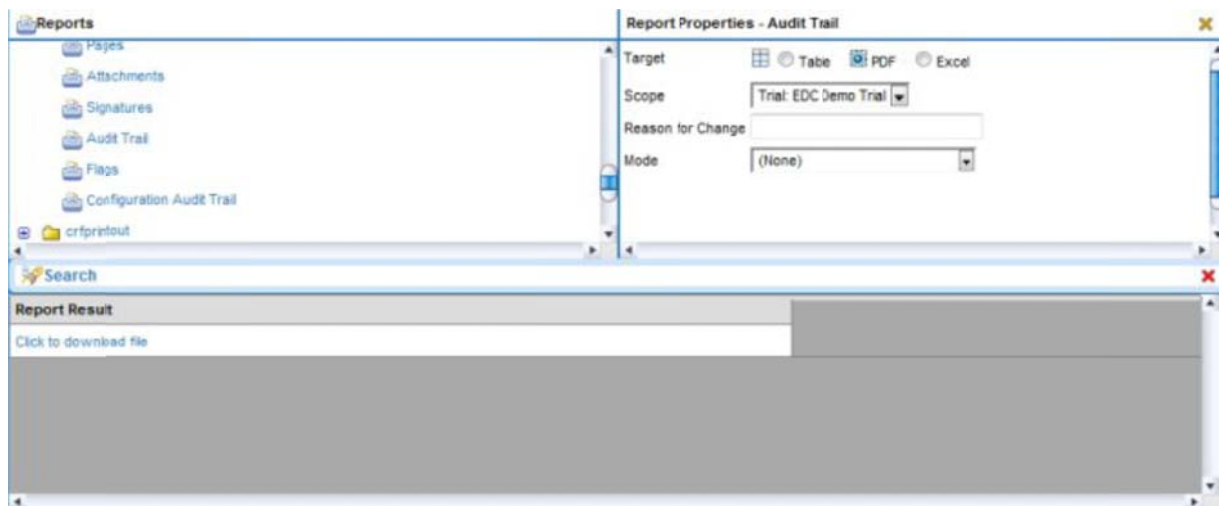
Fig. 59 - Generating the PDF target for the Audit Trail report