

# DFweb User Guide

## DFweb User Guide

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### Abstract

This guide describes the DFweb application.

The instructions are intended to describe, in general terms, how data entry tasks are performed using DFweb. The guidance provided here is not meant to replace more specific instructions which may be provided by the sponsor, principal investigator or coordinating site for a particular trial.

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# Preface

DFweb is a web application delivered through a browser interface. Use of DFweb requires a browser that fully supports HTML5.

## 1. Getting Help

For software support, please contact the DFdiscover team:

- via email, <help@dfnetresearch.com>;
- visit our website, [www.dfnetresearch.com](http://www.dfnetresearch.com).

## 2. Conventions

A number of conventions have been used throughout this document.

Any freestanding sections of code are generally shown like this:

```
# this is example code
code = code + overhead;
```

If a line starts with # or %, this character denotes the system prompt and is not typed by the user.

Text may also have several styles:

- Emphasized words are shown as follows: *emphasized words*.
- Filenames appear in the text like so: `dummy.c`.
- Code, constants, and literals in the text appear like so: `main`.
- Variable names appear in the text like so: `nBytes`.
- Text on user interface labels or menus is shown as: **Printer name**, while buttons in user interfaces are shown as **Cancel**.
- Menus and menu items are shown as: **File > Exit**.

# Chapter 1. Introduction

## 1.1. What is DFweb?

DFweb is a browser-based application that allows users to perform data entry for a DFdiscover study.

## 1.2. Compatible Browsers

DFweb requires a browser with HTML5 capabilities. Check your browser's capabilities at <https://html5test.com>.

DFweb has been tested with current versions of Chrome, Firefox, and Edge on Windows 10 and Chrome, Firefox, and Safari on macOS 10.14 (Mojave) or later. Browser updates are frequently made available by vendors. Please keep your browser up-to-date.

DFweb is not compatible with any version of Internet Explorer, any browser in Windows XP or any browser in Windows 7.

## 1.3. Capabilities

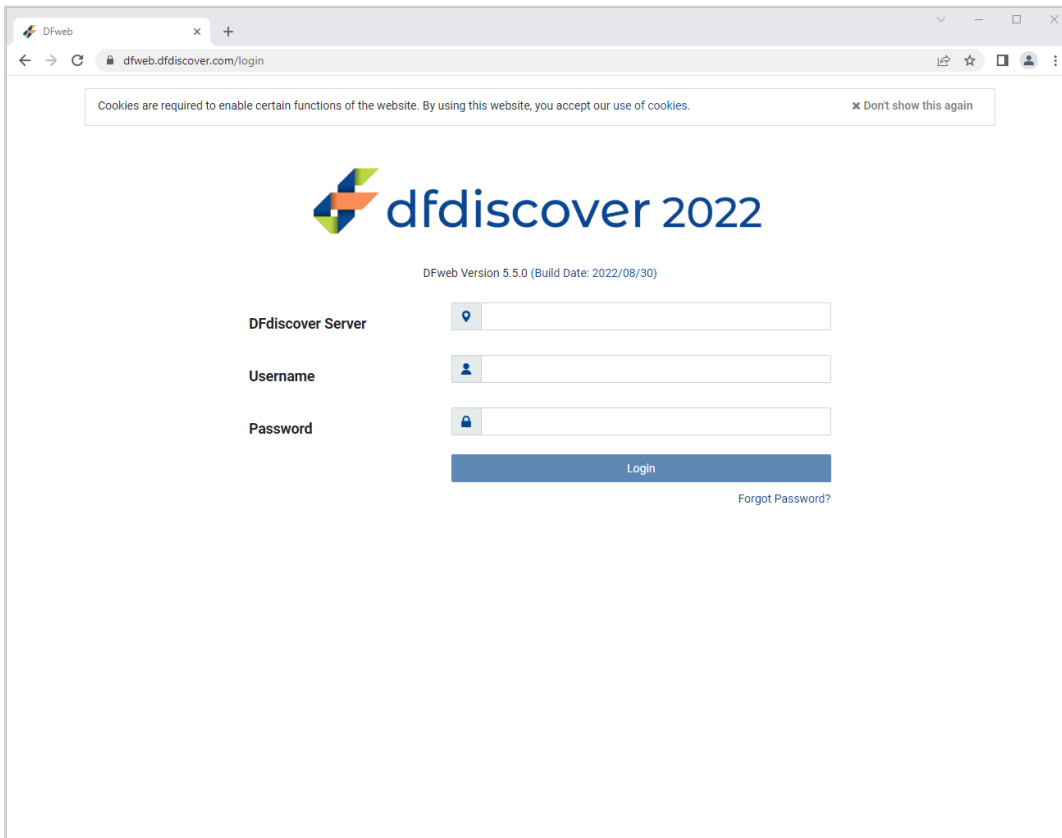
The main purpose of DFweb is to facilitate data entry at clinical sites participating in a DFdiscover study without the need for the additional features available in DFexplore. It may also be that a site is unable to install a local application like DFexplore - DFweb is the perfect solution.

DFweb supports many of the same data validation features as DFexplore - legal range checking, type validation, required values, field skipping, missing value coding and several metadata features - adding, resolving, and editing queries, and adding reasons for data values. It also supports the DFdiscover edit checks language, with a few exceptions.

## 1.4. Getting Started

### 1.4.1. Login Page

The login page is the initial landing page in DFweb. The login page is accessed from any compatible browser via the URL <https://dfweb.dfdiscover.com/login>.

**Figure 1.1. Login Page**

To access a study, a successful login is required. Successful login requires valid credentials. Valid credentials include a value for each of **DFdiscover Server**, **Username** and **Password**. Your study sponsor or monitor has provided you with your own unique credentials. After login, all activities are logged with your username. Do not share your credentials with any other user - each user must use their own credentials.

If you already have login credentials for other DFdiscover tools, the login credentials for DFweb are identical.

Once you have entered a value for **DFdiscover Server**, the login screen may refresh with a standard message from the DFdiscover administrator. This is useful confirmation that you are connecting to the correct server.

Enter your Username and Password exactly as provided. Click **Login** to continue.

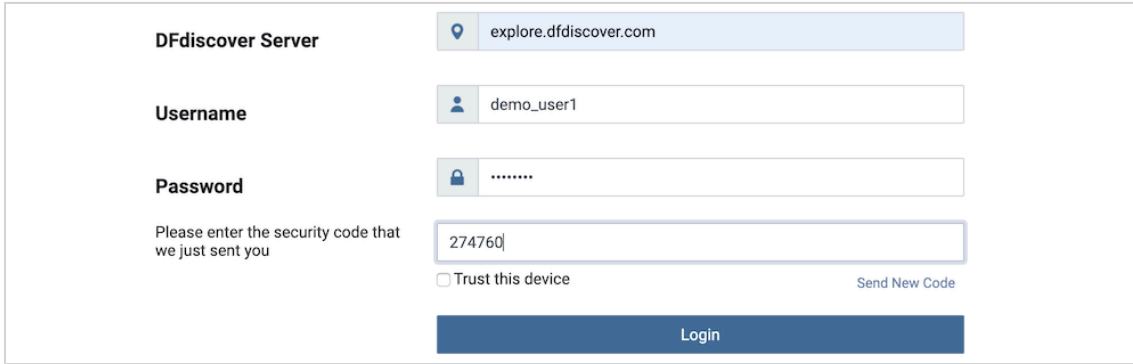
Problems with the login, whether due to a bad password, mistyped server, or anything else, may appear in red text below the login button.

If you don't remember your password, click **Forgot Password** on the login page. Provide the **DFdiscover Server**, **Username**, and **Email** and click **Send Email** to request a new password. You will receive an email with the subject line "DFdiscover password reset". Follow the instructions in that email to reset your password.

When you login for the first time, or if your password expires, you may be prompted to provide a new password. To continue provide a new password meeting the stated requirements.

## 1.4.2. Two-Factor Authentication

The administrator of the DFdiscover Server may have enabled two-factor authentication for your login account. If it is enabled, after successful authentication the login screen updates to request the security code. You will receive an email with the 6-digit security code. The email is sent to the email address on file for the account. Enter the 6-digit security code.



DFdiscover Server: explore.dfdiscover.com

Username: demo\_user1

Password: .....

Please enter the security code that we just sent you: 274760

Trust this device [Send New Code](#)

**Login**

The code is unique to your login on a specific device and is valid for 10 minutes. If you do not receive the email or the code is no longer valid, you can request another code by clicking [Send New Code](#). After entering the code, click [Login](#) to complete login.

If you are using a personal device, you can choose to enable [Trust this device](#). By enabling this setting, you will not be asked for another security code for 30 days. If you are using a shared device, do not enable this setting - this provides an additional layer of security as each login will require a unique security code.

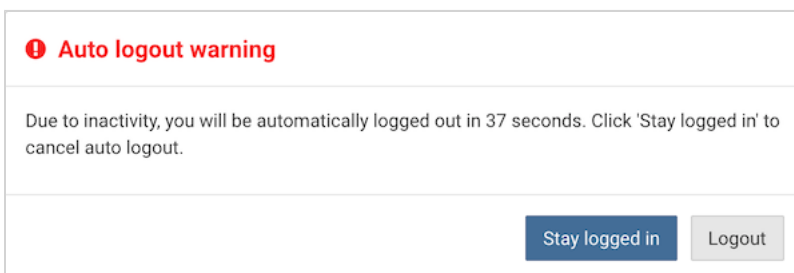
### 1.4.3. Cookies

DFweb uses cookies. Cookies are standard technology implemented in all web browsers. They are small pieces of data sent from a web server (the DFdiscover server in this case) and stored on the user's computer by the user's web browser, while the user is browsing. The login page displays a notification and a hyperlink for more detail.

Further details on the usage of cookies in DFweb can also be found at <https://www.dfnetresearch.com/cookie-policy/>. Click [Don't show this again](#) to confirm that you have read the notification and stop it from being shown in that browser again. If you have previously cleared the notification and need to see it again, clear the browser's cookies and site data, and refresh the page.

### 1.4.4. Session Timeout

To maintain security, the DFweb login session is automatically closed if there is no activity for 20 minutes. A warning, with countdown, is displayed one minute before the session is closed. Click [Stay logged in](#) to continue to use DFweb and reset the timer.



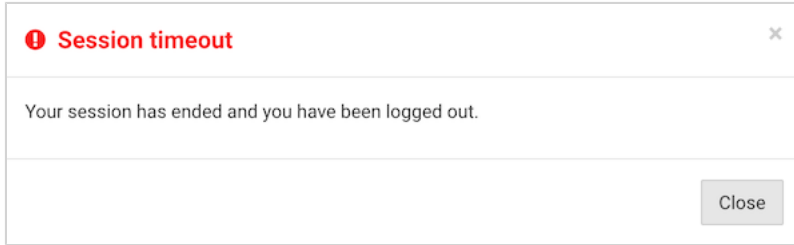
**Auto logout warning**

Due to inactivity, you will be automatically logged out in 37 seconds. Click 'Stay logged in' to cancel auto logout.

[Stay logged in](#) [Logout](#)

In the event of session timeout, the following actions take place:

- an information dialog is presented to notify that automatic logout has occurred



- unsaved changes for the current CRF, if any, are discarded
- the lock for the current CRF, if any, is released
- you are logged out and taken back to the login screen

Never rely upon the session timeout to terminate a session. Always save changes to the current CRF and logout.

## 1.4.5. Logging Out

To exit from DFweb, choose **Logout** from the [Application Menu](#). After successful logout, the login window is shown.

When using DFweb, logging out via **Logout** in the [Application Menu](#) is the recommended and most secure way to exit DFweb. Although closing the page ensures your data is safe, it is best practice to logout properly.

## 1.5. Terminology

A glossary of frequently used terms is presented below.

<b>Document</b>	A document is a file that is, or will be, attached to a CRF. Documents can be images, PDFs, videos or other file types.
<b>eCRF</b>	Electronic case report forms (eCRFs) are CRFs (as described below) where the layout of the fields is handled by DFweb, and where no background image is displayed. eCRFs arrange fields as individual rows in a column, and the layout of the fields adjusts as the window size changes.
<b>Field</b>	A field is a single data value and optional related metadata, including queries, the reason for the data value, possibly a missing value, and other descriptive information about the field, such as its label and help.
<b>Final (Status)</b>	Final is a record status. A record can have status Final if there are no missing required fields, no illegal values and no outstanding queries. DFweb decorates Final records with a green shaded rectangle (see also Incomplete and Pending).
<b>Incomplete (Status)</b>	Incomplete is a record status. A record can be saved with status Incomplete if it has one or more fields which are incomplete (required and missing) or illegal, or outstanding queries. DFweb marks Incomplete records with a red partially shaded rectangle (see also Final and Pending).
<b>Missing Value</b>	A missing value is used to identify a field that is known and accepted as empty. A missing value allows even a required field to be blank and for the CRF to still be saved as Final.
<b>New (Status)</b>	New is a record status. A new record is a placeholder for data that has been entered but not saved yet. It can be a useful reminder for records which are expected but are not yet entered/saved. DFweb marks new records by an empty grey square, circle, or subject icon without a rectangle.

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<b>Paper CRF</b>	Paper case report forms (paper CRFs) are CRFs (as described below) where the fields are laid out with specific sizes and locations relative to a background image. As the positions are fixed, the layout of the fields is not adjusted as the window size changes.
<b>Pending (Status)</b>	<p>Pending is a record status. During entering a new data, a record can be saved with status Pending to indicate that data entry is still in progress, it has been started, not yet finished and you plan to return to it shortly and do not move to higher levels until they are saved with status Final or Incomplete. Pending records are typically not visible to or reviewed by the study coordinating site until they progress to Incomplete or Final status. Pending records are also not generally reported in summary listings.</p> <p>DFweb saves CRFs as Pending after a document has been added to a new CRF but no data entry has been done. DFweb marks pending records with an orange empty rectangle.</p>
<b>Plate, or CRF</b>	Plate and CRF are terms used interchangeably to refer to a logical grouping of data fields, presented with a layout determined by the study sponsor, to fit on a single sheet of paper, or single webpage. Each CRF may stand alone, or CRFs may be grouped into multi-CRFs. A collection of CRFs constitute a visit, and a collection of visits constitute the subject binder, which holds all study data for an individual subject.
<b>Query</b>	A query is a question or comment about an individual data value. The study coordinating site may add a query to any data field to ask a question about the field, or request a correction or clarification. A query is metadata about the data value, or lack thereof, in the field, DFweb identifies query status by applying color to the field. A field with an outstanding query is blue. When a reply is provided to a query, or a reason is added to explain the field, the color is updated to orange, and when the field has been corrected, or the reply or reason have been approved, the color changes to green, provided there are no other outstanding queries on the field.
<b>Reason</b>	A reason is metadata used to explain the value in a data field. It is particularly useful as a way of explaining unusual values and thereby avoiding a data query from the study coordinating site. DFweb colors fields with a new reason orange and gives them a Pending status. If the coordinating site accepts the reason, the field color changes to green and the reason status changes to Accepted. If they do not accept the reason, the field color changes to blue and the reason status changes to Rejected. A reason can be modified, which starts the review process over again.
<b>Save</b>	None of the changes made to a CRF are saved to the study database until you click <b>Save</b> . If you leave the computer without saving your work, DFweb will time-out after a few minutes and any un-saved changes will be lost.
<b>Screen</b>	A screen is an optional grouping of fields on a CRF. On smaller displays, screens can be useful for grouping fields to ensure that they are seen together. DFweb indicates screens using a tab, and multiple screens in a CRF are stacked vertically.
<b>Subject</b>	A subject is an individual participating in a clinical study and for whom data is collected. Subjects are identified by subject ID (a unique numeric identifier), according to conventions established by the study coordinating site.
<b>Subject Binder</b>	A subject binder contains all of the required and optional data collection forms used to collect study data for an individual subject. Within DFweb, subject binders are displayed in a list by subject ID, with an associated icon that indicates whether the binder is empty or contains recorded data, and whether that data is currently Final, Incomplete or Pending.
<b>Visit</b>	A visit is a study timepoint at which one or more CRFs for a subject are completed, or a repeating log form such as an adverse event or concomitant medications. The duration of a

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subject's participation in a study is often marked by a baseline visit, several repeating visits, and a termination visit.

# Chapter 2. Data Entry

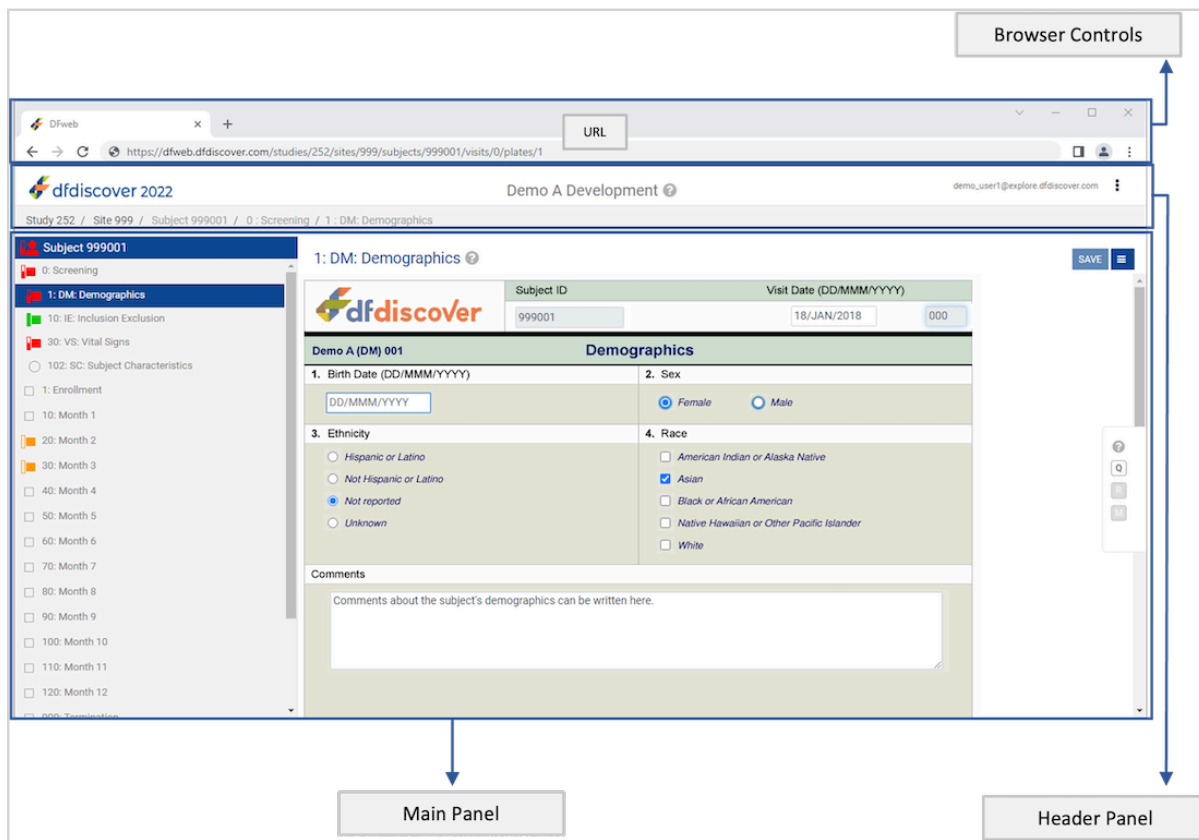
## 2.1. Main Application Pages

DFweb includes several key pages which are explained here. More detailed explanations of certain pages and functionality, as well as the menus and dialogs that appear on these pages are given in the following sections.

### 2.1.1. Overall Application Appearance

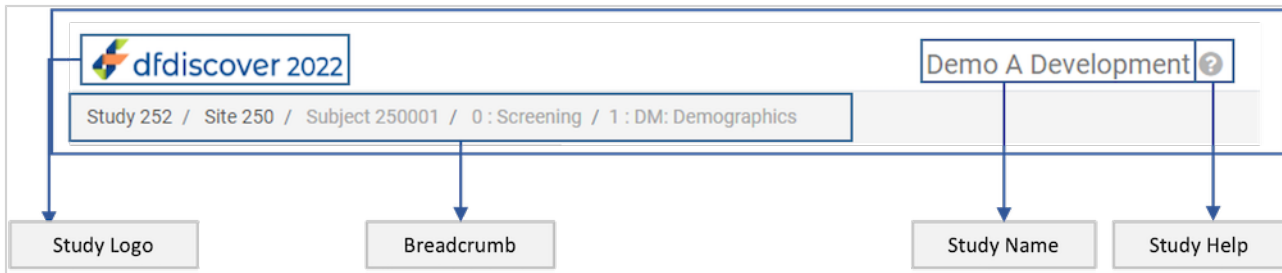
After logging in, you will be taken to the Studies Page. The Studies Page and other pages in DFweb share a similar layout.



**Figure 2.1. Application Layout**

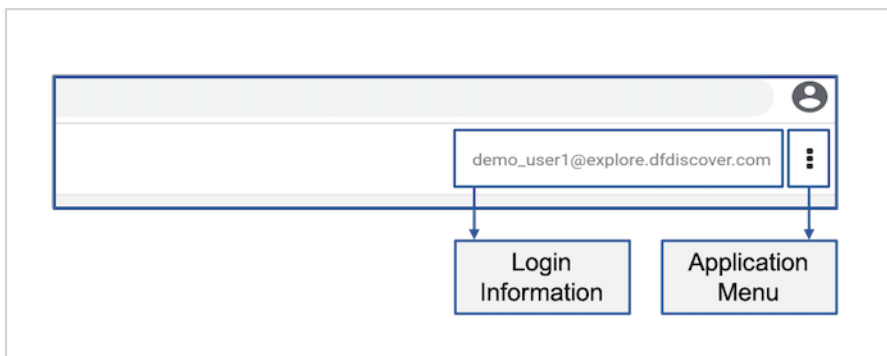


The following features appear in the application layout:

- **Browser Controls.** Browser controls are specific to each browser and are not part of DFweb. In general, this area contains the URL for the content that is being viewed, buttons to move to the previous page (if one exists), the next page (if one exists) and refresh the current page, and controls for tabbed windows (if supported).
- **Header Panel.** The header panel is available on all pages of DFweb except the login page. It contains options and navigation that are relevant for all pages, including:

**Figure 2.2. Header Panel, Left**

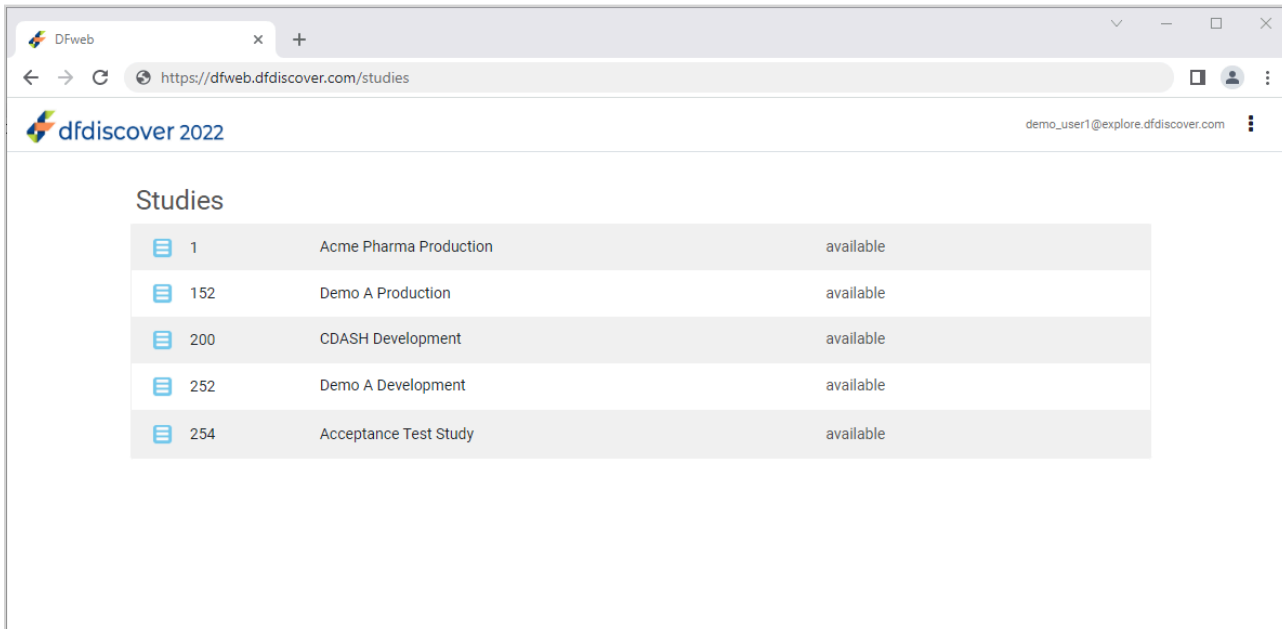
- **Breadcrumb.** The breadcrumb is a navigation aid displaying information about the current context as well as simplifying access to other pages in the study via clickable links.
- **Study Logo.** If the study defines a study logo, it appears in the header panel. Otherwise, the DFdiscover logo is displayed.
- **Study Name.** This is the name of the selected study. On the studies page, before you have selected a study, this is empty.
- **Study Help.** If study help has been defined,  appears in the header panel. Click it to display the [Study Help Dialog](#).
- **Login Information.** Your username and DFdiscover server appear in the header panel with the format [username]@[server]. On small displays, this information is visible from the application menu, .
- **Application Menu.** The application menu contains several generic functions that are not study specific, including [Logout](#). See [Application Menu](#) for more information.

**Figure 2.3. Header Panel, Right**

- **Main Panel.** The main panel contains the primary information and interaction for the current page. Pages that may appear here are the [Studies Page](#), [Sites Page](#), [Subjects Page](#), and [Subject Binder](#).

## 2.1.2. Studies Page

Figure 2.4. Studies Page



The screenshot shows a web browser window with the URL <https://dfweb.dfdiscovers.com/studies>. The page title is "Studies" and the user is logged in as "demo\_user1@explore.dfdiscovers.com". The table below lists five studies, all with a status of "available".

Study ID	Study Name	Status
1	Acme Pharma Production	available
152	Demo A Production	available
200	CDASH Development	available
252	Demo A Development	available
254	Acceptance Test Study	available

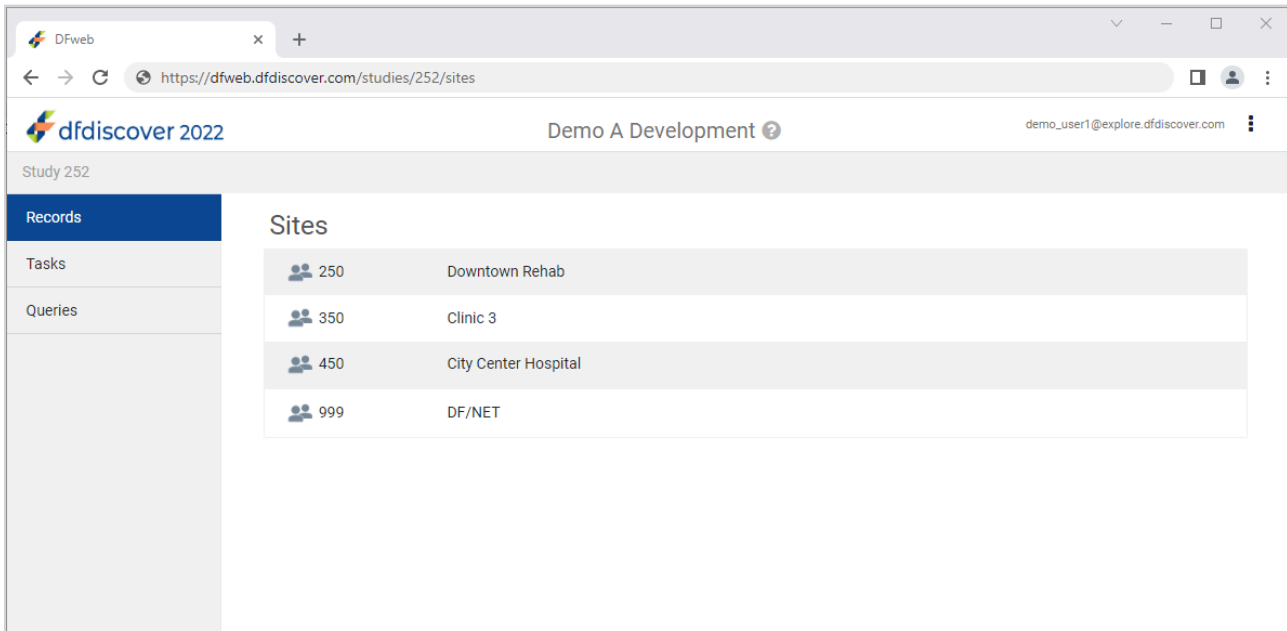
The Studies Page is displayed after successful login. It lists the studies you have permissions for. Click one of the available studies to choose that study as the current study. This takes you to the Sites Page for that study.

If you have permissions for exactly one study, this page is bypassed, going to the Sites Page.

The study's number, name, and status are displayed on each line. If the study is not available, the reason is displayed in red in the status column. Not all issues can be discovered before entering the study. If such a problem exists, after selecting the study you are notified of the issue with an alert dialog and returned to the studies page, where the issue is also presented in the status column.

## 2.1.3. Sites Page

Figure 2.5. Sites Page

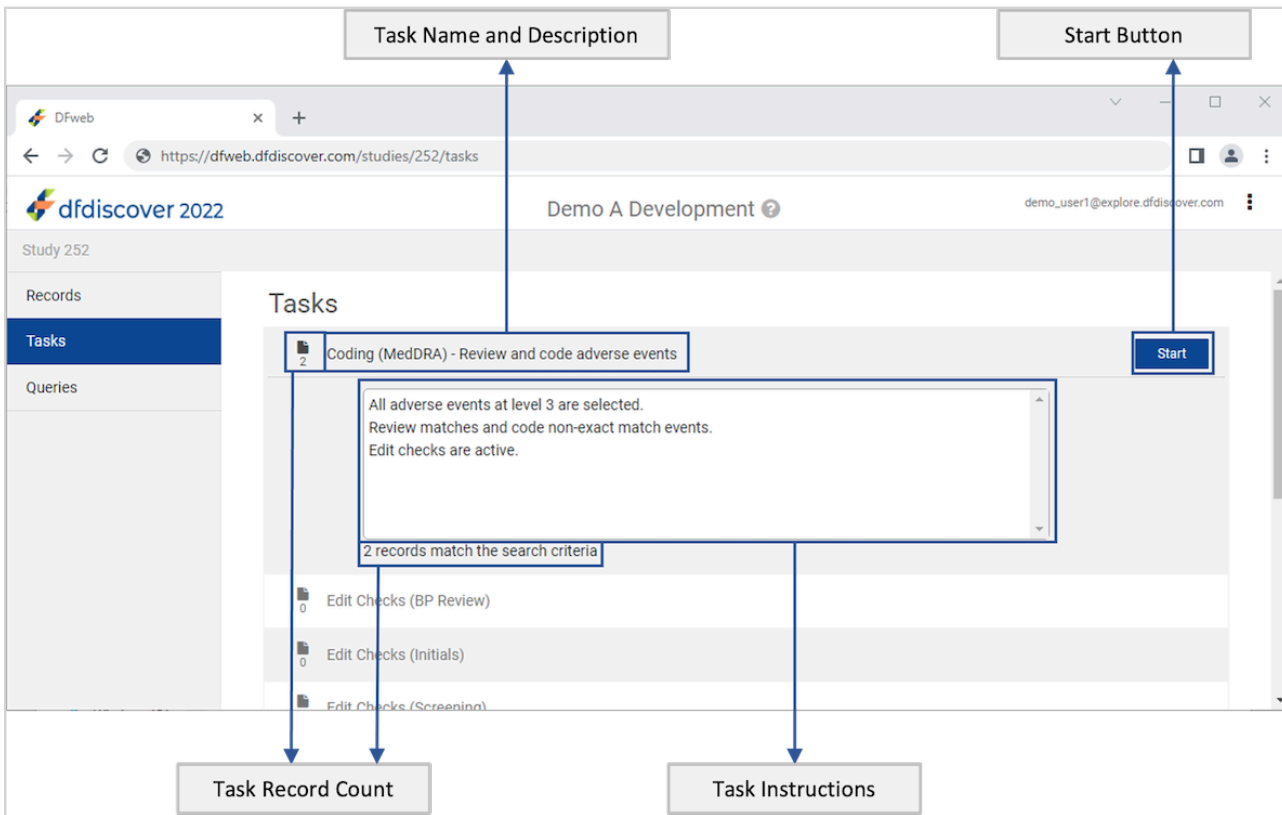


The Sites Page contains a list of the sites you have permission for. The site number and label are shown on each line. Click one of the sites to make it the active site. This takes you to the Subjects Page for that site.

If you have permissions for exactly one site, this page is bypassed, going to the Subjects Page.

## 2.1.4. Tasks Page

Figure 2.6. Tasks Page

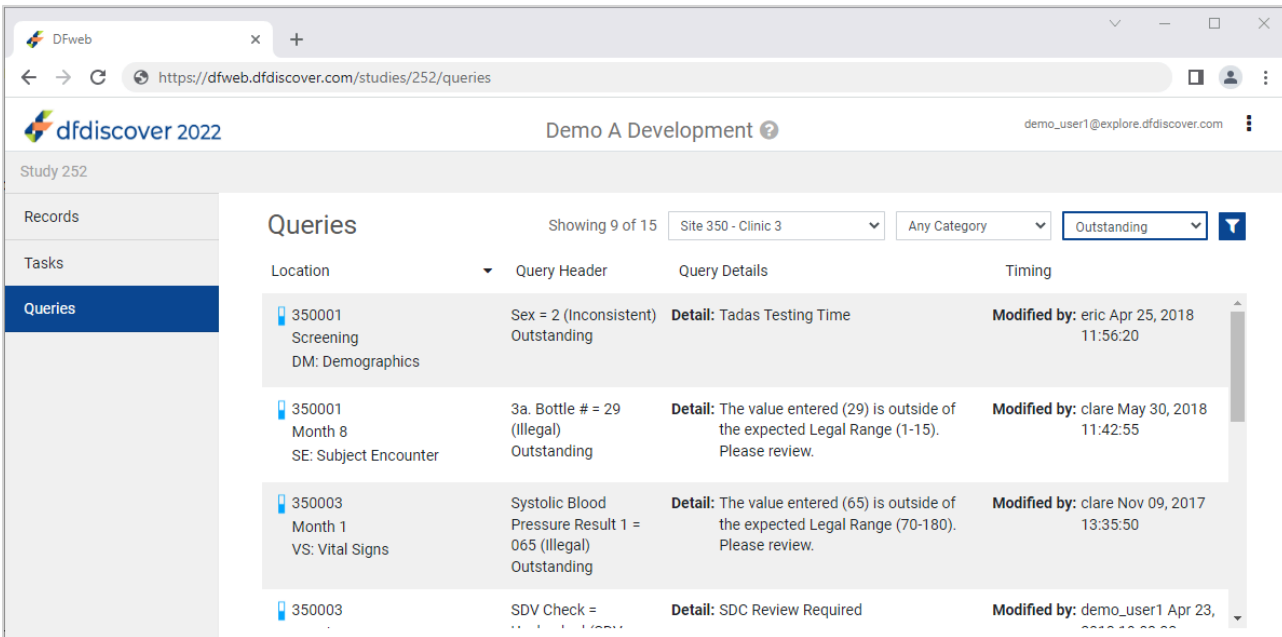


The tasks page is accessed by selecting **Tasks** from the left-hand sidebar. It contains a list of the tasks you can run. Click on a task title to view any details and click **Start** to start the task.

For more details on how to use tasks in DFweb, see [Tasks](#)

## 2.1.5. Queries Page

Figure 2.7. Queries Page

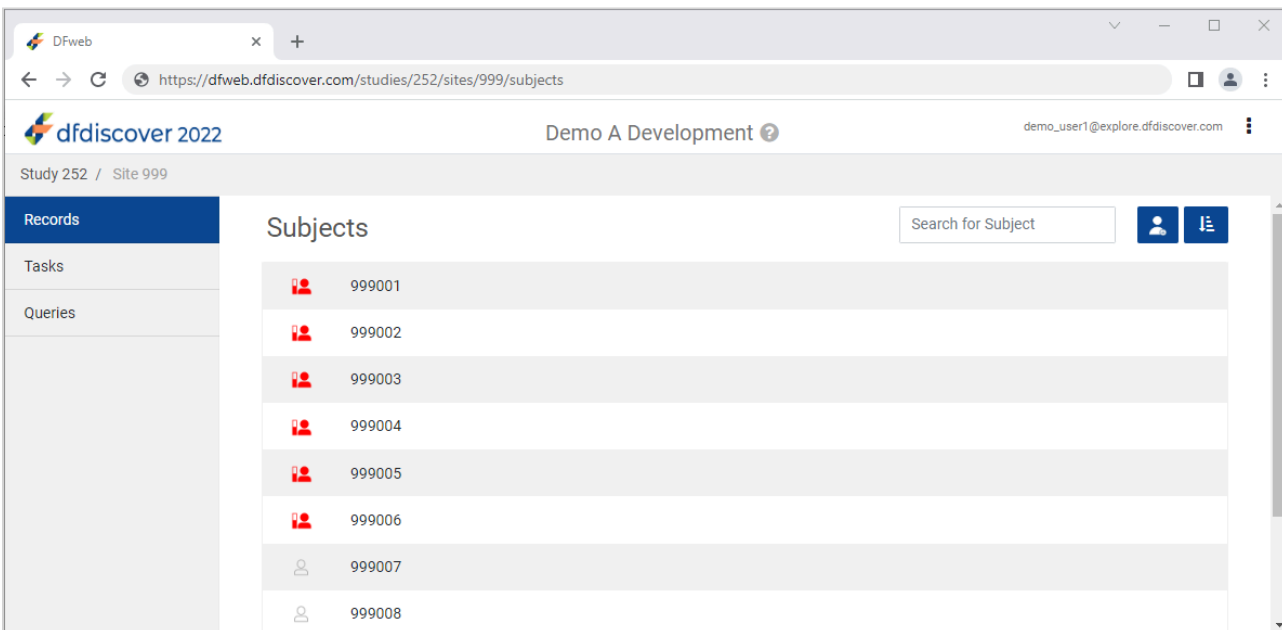


The queries page is accessed by selecting **Queries** from the left-hand sidebar. From this page you can browse all the queries in the study. Double-click a query to open the CRF and place the focus on the field with that query.





For more details on how to use the queries view in DFweb, see [Queries View](#)

## 2.1.6. Subjects Page

Figure 2.8. Subjects Page








The Subjects Page contains a list of permitted subjects. Click a subject to open the subject binder. The icon to the left of the subject ID shows the current status of the subject binder. The status may change over the duration of the study as more visits become required and further data review takes place.

-  The subject binder is final, all data required at this time has been submitted, and there are no outstanding responses or missing, required values.
-  The subject binder is incomplete. There may be missing, required values, illegal values or unresolved questions about the data.
-  The subject binder is pending. There is at least one document attached to the subject ID, but otherwise there is no data yet.
-  There is no data for this subject, or the subject has not yet been saved.

50 subjects are displayed by default. Click [Show More](#) to show all subjects. Click [Show Less](#) to return to the first 50.

The Subjects Page also provides the following functionality:

- **Search Bar.** The search bar allows you to quickly navigate to a subject with a given subject ID. As you type, the list of subjects automatically filters to show only those subjects containing what you have entered. Click **Enter** to open the Subject Binder for the first filtered subject.
- **Add Subject.** Click  to open the [Add Subject Dialog](#).
- **Sorting.** Click  or  to change the sort order. This toggles between increasing and decreasing subject ID ordering.  indicates that currently the subject IDs are sorted numerically in ascending order.  indicates that the current sort order is descending.


### 2.1.6.1. Finding Subject Records

To return to the Subjects list from a subject binder, click the site number in the breadcrumb.

The Subjects list displays up to 50 subjects at a time. Click [Show More](#) to display additional subjects. To search for a specific subject ID, use the Search Bar.

### 2.1.6.2. Selecting a Subject

On the Subjects page, click a subject ID from the list to open the subject binder.

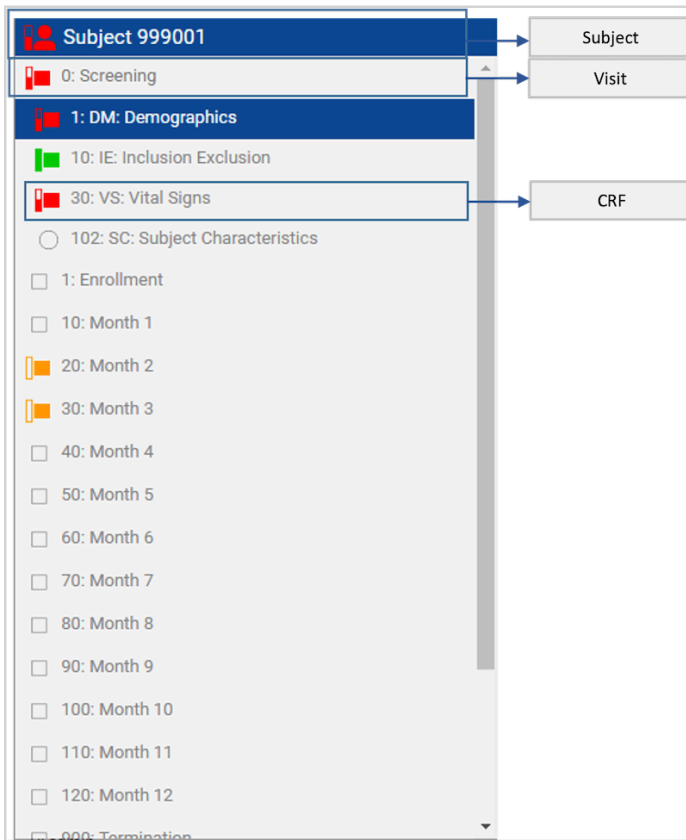
If the subject ID you need is not in the list, click  to add a new subject. This opens a dialog with two text input fields. Enter the subject ID to add to the current site. Confirm the subject ID by entering it again. Click [OK](#) to confirm the subject creation, or [Cancel](#) to close the dialog without creating a subject.

### 2.1.7. Subject Binder

The Subject Binder contains all the information of the visits and plates related to a subject. The initial page you are taken to is the first visit and CRF for the subject.









### 2.1.7.1. Sidebar




**Figure 2.9. Subject Binder Sidebar**



The sidebar displays the current subject, visit, and CRF, as well as providing navigation between CRFs and visits. The current subject is displayed at the top of the sidebar. The rest of the sidebar displays all the visits for this subject that you have permission to view. The current visit is expanded to show all the CRFs in that visit that you have permission to view. CRFs are indented slightly from the visits to help visually differentiate them. CRF and visit labels follow the format [Number]: [Label].

Each visit and CRF has an icon that displays its current status. The meanings of the icons are:

-  - This CRF or visit is final, and it is a required CRF or visit.
-  - This CRF or visit is incomplete, and it is a required CRF or visit.
-  - This CRF or visit is pending, and it is a required CRF or visit.
-  - This CRF or visit has not been saved, and it is a required CRF or visit.
-  - This CRF or visit is final, and it is an optional CRF or visit.
-  - This CRF or visit is incomplete, and it is an optional CRF or visit.
-  - This CRF or visit is pending, and it is an optional CRF or visit.
-  - This CRF or visit has not been saved, and it is an optional CRF or visit.

-  - This CRF or visit is final, and it is an unexpected CRF or visit.
-  - This CRF or visit is incomplete, and it is an unexpected CRF or visit.
-  - This CRF or visit is pending, and it is an unexpected CRF or visit.

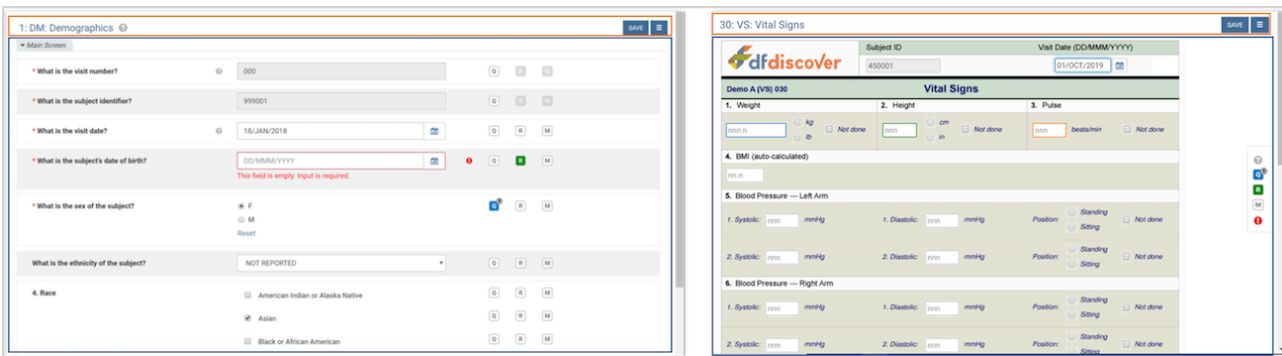
Click a CRF in the current visit to make it the current and displayed CRF. Click another visit to make that visit current and to display the first CRF in that visit.

### 2.1.7.2. Form

The main part of the page contains the data entry form. This form allows you to view, add and modify data, queries, reasons, and missing values, and view and add documents to the form.

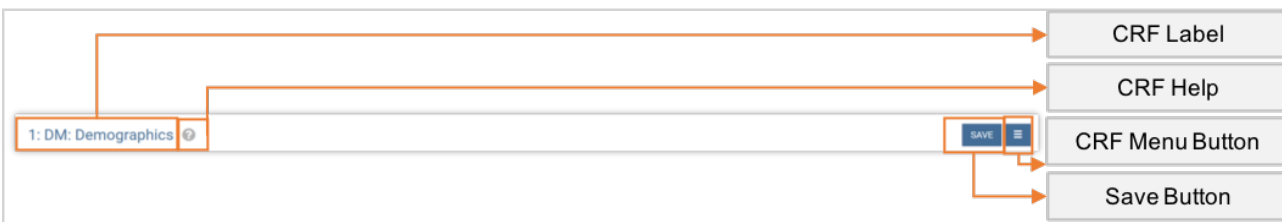
Data entry forms on DFweb can be presented as either eCRFs or paper CRFs, depending on the study setup for the plate. Both types of forms contain a header section and a data entry section.

**Figure 2.10. Data Entry Form**





At the top of the form is a header area for CRF-wide actions. The header remains visible as you scroll through the CRF contents.

**Figure 2.11. Data Entry Form Header**



The header contains:

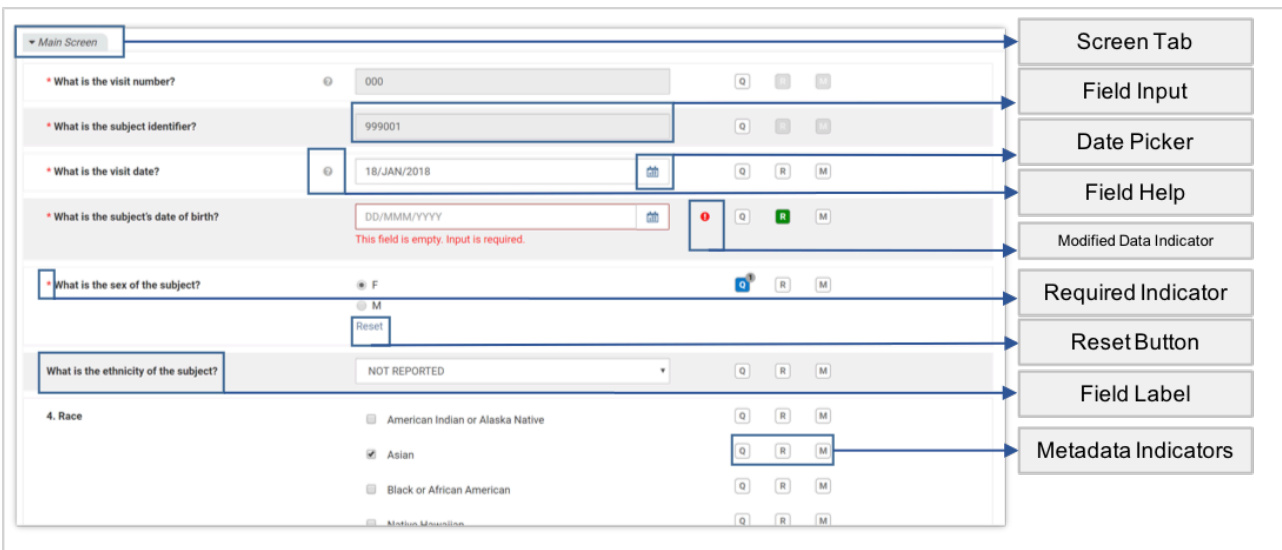
- **CRF Label.** The CRF label is composed of the CRF number and label. These follow the format [Number]: [Label].
- **CRF Help.** If CRF help has been provided for this CRF in the study setup,  appears in the header area. Click to open the [CRF Help Dialog](#).
- **Locked CRF Icon.** If the CRF is in use by another user,  appears to the left of **Save**. This indicates that no editing can be done on this CRF.

- **CRF Menu Button.** Click or to open the **CRF Menu**, which contains CRF level options such as managing documents and resetting the data entry form.
- **Save Button.** Click **Save** to save the changes you have made to the current CRF and submit them to the server. **Save** is disabled if no changes have been made to the form. Hover your mouse over **Save** to display a tooltip with the last saved time and the CRF status.

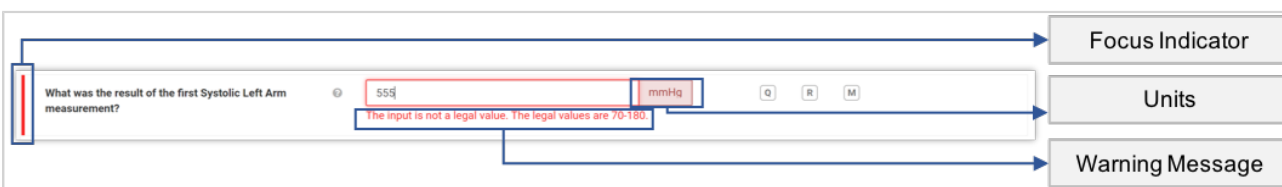
### 2.1.7.2.1. eCRF

On an eCRF, the remainder of the form is filled by screens, which appear as vertically stacked tabs. Click the corresponding tab to close any screen. The tab with the input focus cannot be closed.

**Figure 2.12. eCRF Data Entry Form**



**Figure 2.13. eCRF Data Entry Form 2**



Each screen is composed of rows of fields. Each field can contain:

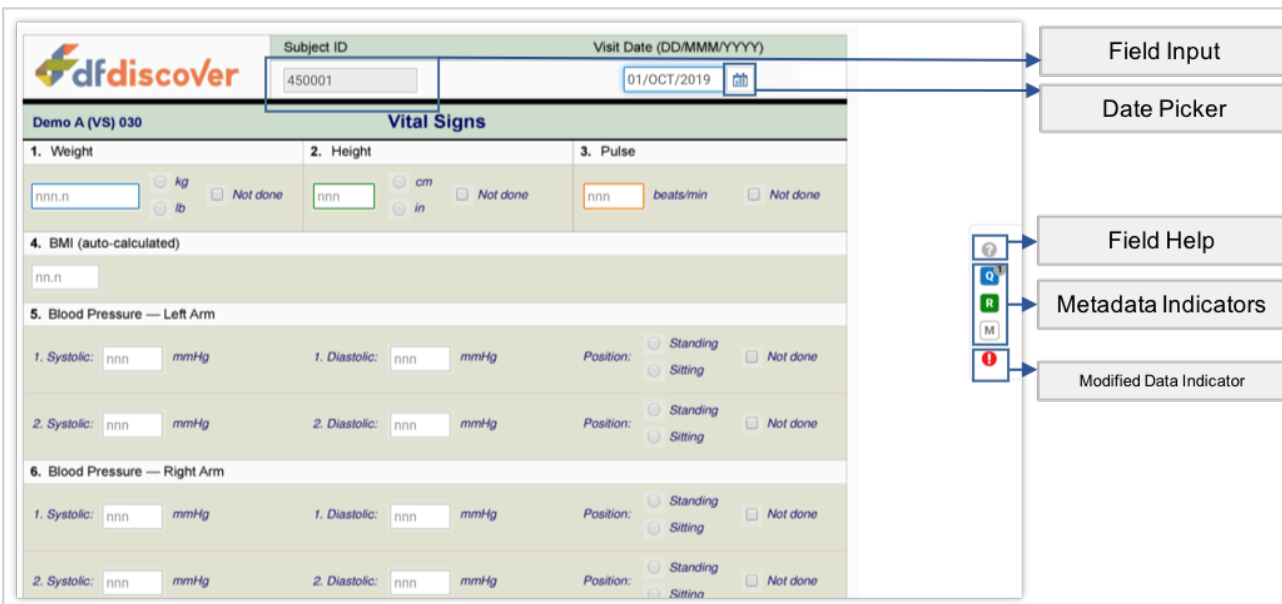
- **Field Input.** Each field has an input area. The type of input determines exactly what appears in this area. For more information on input types, see [Data Types](#).
- **Date Picker.** Date fields have a date picker ( ). Click to reveal a calendar. Picking a date in the calendar is equal to typing it in the Field Input.
- **Field Help.** If the study setup has defined help for the field, is visible. Click to display a help tooltip, which can be dismissed by clicking any other area of the page.
- **Modified Data Indicator.** If a value in the field is unable to be displayed in the input area, it is modified when you open the CRF. shows which fields have been modified. Click the indicator to display more information about the change.

- **Required Indicator.** If the field is required or essential, \* appears on the line. Fields with this indicator display a warning message if left blank.
- **Reset Button.** Choice (Radio Button) and VAS input areas have **Reset**. This can be used to set the field back to the blank value.
- **Field Label.** The field label shows the field prompt, if it is available. Otherwise the field description is used for the label.
- **Metadata Indicators.** **Q**, **R**, and **M** are displayed on each line. They allow the user to add, modify and view queries, reasons and missing values for that field. For more information on queries, reasons, and missing values, see [Chapter 3, Metadata](#).
- **Focus Indicator.** A colored bar indicates that the field is in focus, and the color indicates the status of the field. To learn more, see [Focus Indicators](#).
- **Units.** If units are defined for the field, they are shown in or near the input area. Where they are displayed depends on the type of input.
- **Warning Message.** Warning messages appear when issues like illegal field values, missing values, or incorrectly formatted information are present in the field. Correct the issue to remove the message.

### 2.1.7.2.2. Paper CRF






On a paper CRF, each plate is displayed as fields laid out on a background image, and a metadata icon panel floats to the right of the window. The metadata icon panel represents metadata for the currently focused field.

**Figure 2.14. Paper CRF Data Entry Form**




A paper CRF can contain:

- **Field Input.** Each field has an input area. The type of input determines exactly what appears in this area. For more information on input types, see [Data Types](#). Field inputs on paper CRFs can have colored borders. For more information on the borders, see [Locating Metadata](#).
- **Date Picker.** Date fields have a date picker (📅) that becomes visible when the field is focused. Click to reveal a calendar. Picking a date in the calendar is equal to typing it in the Field Input.

- **Field Help.** For the field that is currently focused, if the study setup has defined help for the field,  is visible in the metadata icon panel. Click to display a help tooltip, which can be dismissed by clicking any other area of the page.
- **Metadata Indicators.** , , and  are displayed in the metadata icon panel. They allow the user to add, modify and view queries, reasons and missing values for the field that is currently focused. For more information on queries, reasons, and missing values, see [Chapter 3, Metadata](#).
- **Modified Data Indicator.** If a value in the field is unable to be displayed in the input area, it is modified when you open the CRF. For the field that is currently focused,  in the metadata icon panel shows that the field has been modified. Click the indicator to display more information about the change.
- **Focus Indicator.** When a field is in focus, the outline color indicates the status of the field. To learn more, see [Focus Indicators](#).

### 2.1.7.2.3. Locking

When you enter a subject binder and the CRF becomes visible, DFweb attempts to establish a lock on the CRF. If it succeeds, you gain the lock on the CRF and other DFdiscover apps won't be able to edit the CRF until it is unlocked. If someone else already has the lock, your attempt fails and you are shown the locked CRF in read-only mode.

A locked CRF is indicated by a  beside the save button. When a CRF is locked, all data fields are in read-only mode, meaning no data can be entered, and no queries, reasons, or missing values can be added to the field. Existing queries, reasons, and missing values can still be viewed by clicking the appropriate button, however all input fields and actions other than cancel are disabled. The Manage Documents dialog is accessible for document review, however no new documents can be uploaded to a locked CRF. Finally, [Save](#) and [Reset Page](#) are disabled on a locked CRF.

Exiting a CRF, whether by navigating to another CRF, exiting the subject, or logging out, unlocks the CRF.

## 2.2. Entering Data / Completing a Record

### 2.2.1. Data Entry Aids

#### 2.2.1.1. Keyboard Navigation

Navigating from field to field is possible using the Tab key. The [Save](#) button, if enabled, is tabbed to after the last field. Within choice fields (shown as either radio buttons or dropdowns), the up and down arrow keys can be used to switch between options, and the option can then be selected using the Space key. Within visual analog scale (VAS) fields, the left and right arrow keys can be used to select a point on the scale.

#### 2.2.1.2. Focus Indicators

The last in-focused field displays a vertical bar on the left edge of the field (for eCRFs) or a field highlight/outline (for paper CRFs). It may have color information, including red (required and missing or illegal values), blue (outstanding query), green (resolved), orange (pending), and black (otherwise). The current active field is outlined; on eCRFs, the highlight color matches the vertical bar, except in the case of a black vertical bar, in which case the highlight color is the default one for the browser.



#### 2.2.1.3. Formatting

Some fields only accept specific data formats. Field formatting is shown in the blank field to help guide data entry. For example, a date field may have the format YYYY/MM/DD or a lab result field may have the format nn.nn.

### 2.2.1.4. Legal Ranges

Some fields may have legal ranges defined. If you enter an illegal value, you are shown a warning similar to: "The input value is not a legal value. The legal values are 01-JAN-2018~today." Correcting the value removes the warning and avoids queries.

### 2.2.1.5. Help

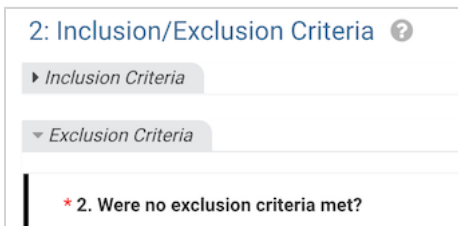
In addition to the description for each field on the CRF, Help information may be available for each field. This is indicated with a  icon. eCRFs display this next to the field label. Paper CRFs display it in the metadata icon panel. Click  to view the Help message.


### 2.2.1.6. Field Skipping

When navigating fields on a CRF using the Tab key, some fields may be skipped. This indicates that the field skipped is not required and can remain blank.

### 2.2.1.7. Screens

Some eCRFs may be divided into multiple screens. A screen has a main body for data as well as a clickable tab to control visibility. In the tab, click the arrow to collapse the fields within that screen, and click again to expand. By default, all screens are expanded when you open a CRF. The tab with the input focus cannot be closed.



2: Inclusion/Exclusion Criteria 

▶ Inclusion Criteria

▼ Exclusion Criteria

\* 2. Were no exclusion criteria met?

### 2.2.1.8. Clearing Data

In fields where you can type a value, deleting the value is sufficient to clear the data. In check fields, removing the check removes the value. In choice and VAS fields however, other methods are provided to clear the data.

In an eCRF plate, click **Reset** on choice and VAS fields to clear the data.

On paper CRF plates, **Reset** is not available. Instead, the field is reset using the missing value dialog. Enter the missing value dialog, and select **No Code (Reset)** from the **Code** dropdown. Click **Apply** to close the dialog and remove the current field value.

## 2.2.2. Data Types

### 2.2.2.1. Number

Numeric digits (0-9), decimal (.), and a sign symbol (+ or -) can be entered in number fields. If a decimal or other character is required, it can be typed directly. Otherwise, it is entered automatically to match the required format for the field.

### 2.2.2.2. String

Any text may be entered in a string field. A maximum field length may be defined which limits the number of characters that can be entered.

If the maximum length for the string is longer than the input area can display, the string field will show as a resizeable field.

## Note

Resizing input areas is impossible on Microsoft Edge. However, the entire text can still be edited, and hovering over the input will display a tooltip with the entire text for easier reading.

### 2.2.2.3. Date

Enter dates using the keyboard, or use the date picker to select a date. The date picker is always visible on date fields in eCRF plates. On paper CRF plates, the date picker becomes visible when the date field is focused. The date picker can be scrolled using the scroll wheel on the mouse, and clicking the month name will enter a condensed view to speed up scrolling. Click a month to exit the condensed view. If a date is entered using the keyboard, it must follow the defined format, e.g. DD-MMM-YYYY, YYYY/MM/DD, DDMMYY. Partial dates may only be entered via the keyboard.

### 2.2.2.4. Time

Enter the time using hours, minutes, and seconds as indicated in the field format.

### 2.2.2.5. Choice

Only one response option can be selected for each choice field. The field displays as radio buttons or a drop-down menu according to the study setup.<sup>1</sup> To remove a response, click **Reset** below the field (eCRFs only), or select **No Code (Reset)** from the missing Value dialog.

### 2.2.2.6. Check

A check field can be checked or unchecked. Multiple check fields may be included in one item; check all that apply.

### 2.2.2.7. Visual Analog Scale (VAS)

Select a point along the scale using the cursor or the left and right arrow keys on the keyboard. On eCRFs, the selected value is shown under the scale in the middle, with the first and last options in the scale shown on the left and right respectively. Paper CRFs display the selected value directly under the scale indicator. To remove a response, click **Reset** below the field (eCRFs only), or select **No Code (Reset)** from the Missing Value dialog.

## 2.2.3. Missing Data

It can occur during data entry that the response to a question is not available. The question may not be relevant, the response is unknown or not applicable, or the response may only be available in the future. With the exception of data fields that are identified as essential, the response for any data field can be recorded as missing. While performing data entry it is important to mark the response for such a data field as missing, rather than leaving it blank. If left blank, a query will be raised during review - was the data field simply skipped or ignored, or was it considered and there is a reason why there is no response? To prevent this uncertainty, missing data must be appropriately identified. Conversely, if data was previously marked as missing and has since become available, the missing designation must be removed and the available data entered. For both situations, the steps are described in [Mark a Data Value as Missing](#).

## 2.2.4. Edit Checks

Edit checks are defined during study setup. They are fragments of logic that enforce study expectations for the data collected. They run interactively during data entry and data review. Edit checks may be run when you enter a CRF or a field, or when you leave a CRF or a field. Edit checks perform various actions, such as displaying messages, adding a query, masking a field, calculating data, or changing data to view only.

<sup>1</sup>If connecting to a DFdiscover 2019 (or older) server, the field is displayed as radio buttons if there are three or fewer response options, and a drop-down menu otherwise.

The following is an example edit check. Your own study will likely have similar edit check that also masks other fields based on the answer of current field. In the edit check example shown below, the edit check has detected the answer of "Were all inclusion criteria met?" is Yes after field exit. The edit check thus masks the following two fields as there is no need to continue to answer them.

## 2.2.5. Saving Data

When you have completed data entry on a CRF, you must save your changes before leaving the CRF. To do so, click **Save**, located near the right side of the header area.

If you leave the CRF before saving, the following dialog is presented:

Select **Stay on page** to remain on the CRF and save your changes. Select **Leave Page** to discard the data on the CRF. Your changes are not saved and cannot be retrieved.

### 2.2.5.1. Working Modes and Workflow Levels

Modes and levels in DFweb are set by edit checks or tasks, and always respect the user's permissions. The current mode and save level can be found by hovering the mouse over the save button. See [DFExplore User Guide, Changing Mode and Level](#) for more details on modes and levels.

## 2.2.6. Electronic Signature

If the CRF you have saved requires an electronic signature, after clicking **Save**, a dialog will appear indicating that the page is eligible for signing.

**This page is eligible for signing**

By entering your username and password, you are executing your electronic signature, which is the legally binding equivalent of your handwritten signature. Your electronic signature on this form indicates that you confirm that the information provided is accurate and true, according to site operating procedures and Good Clinical Practice (GCP) guidelines.

Enter password:

Username

Password

Provide your username and password and click **Sign** to execute your electronic signature and save the CRF. The eSignature fields on the CRF (signature, date, time, reason) will be autofilled on the CRF once signed. The eSignature fields cannot be manually entered or changed during data entry.


You have a limited number of tries to enter the correct username and password. If you provide an incorrect password more than the number of tries indicated, the CRF changes will not be saved and you will be automatically logged out of DFweb.

If you do not want to sign the record, click **Do not Sign** to save the CRF without providing your signature. Click **Cancel** to return to the CRF without saving your changes.

Once you have signed one CRF, you will only need to provide your password when you sign additional CRFs during that login session.



If data on a signed CRF changes after it was signed, it will need to be signed again.

## 2.2.7. Viewing Page History

You can view the history of changes made to a CRF (audit trail) using the Page History option. On any saved CRF, click  to open the CRF menu and select **Page History** to view the history of changes for the current CRF page.

Page History	
<b>Field: Visit Date</b>	
2020-08-11 14:48:06	lisa entered data "03/AUG/2020"
<b>Field: Were vital signs collected?</b>	
2020-08-11 14:48:06	lisa entered data "Yes"
<b>Field: Weight</b>	
2020-08-11 14:48:06	lisa entered data "189.5"
<b>Field: Weight Unit</b>	
2020-08-11 14:48:06	lisa entered data "lb"
<b>Field: Height</b>	
2020-08-11 14:48:06	lisa entered data "65"
<b>Field: Height Unit</b>	
2020-08-11 14:48:06	lisa entered data "in"
<b>Field: Oral Temperature</b>	
2020-08-11 14:48:06	lisa entered data "39.5"
	lisa created "illegal" query with Detail "Oral Temperature has a value of 39.5, which is inconsistent with our expected legal range of 36.1~37.9. Please verify that this value is correct.", Type "Correction", Reply "Confirmed", Use "External"
<b>Field: Pulse Rate</b>	
2020-08-11 14:48:06	lisa entered data "075.0"
<b>Field: Systolic blood pressure</b>	
2020-08-11 14:48:06	lisa entered data "095"
<b>Field: Diastolic blood pressure</b>	
2020-08-11 14:48:06	lisa entered data "100"
	lisa created "illegal" query with Detail "Diastolic blood pressure has a value of 100, which is inconsistent"

The Page History dialog displays a table with a list changes to the data and metadata for each field on the CRF page. The details include the username of the person making the changes and the date and time of the change. All changes to a field are grouped together under the field description header. If a field is currently selected on the CRF, that field will be outlined in blue in the Page History dialog.

Click  to sort the changes from newest to oldest or oldest to newest within each field. Click  to close the dialog and return to the data entry screen.

Page History is only available when **DFweb** is connected to DFdiscover server and API version 5.5 or later.


## 2.2.8. Reset Page

Select **Reset Page** from the CRF menu to undo all unsaved changes and reset the CRF to the last saved database values. This can be useful if you are interrupted during data entry and lose track of where changes have been made. After confirmation, unsaved changes to data, queries and reasons are discarded.

## 2.3. Responsive Elements

DFweb adapts the content to fit displays of different sizes. Largely this is done by adjusting the spacing on the page, however greater changes are made when the display becomes too small. Some of the more significant changes are detailed here.

### 2.3.1. Sidebar Visibility

To allow more room for data entry, the sidebar is hidden on small displays. When it is hidden, a new button with the hamburger (3 line) icon is added beside the page title or CRF label. Clicking this button opens the sidebar. With the sidebar open, click  to hide the sidebar.

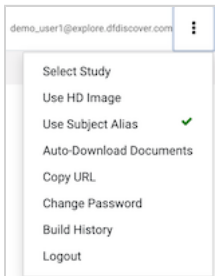
## 2.3.2. Field Arrangement

On small displays, the organization of the fields on eCRFs also changes. The input area, date picker, units, reset button, and warning message are moved below the rest of the elements of the field, allowing enough room for all elements to be visible and usable. Paper CRF field layouts remain the same on small screens.

## 2.4. Menus

### 2.4.1. Application Menu

The application menu provides functionality that is applicable for the entire study or user session. The following functions are available:



- **Select Study.** Select **Select Study** to navigate you back to the study list page. This option is only available when you have selected a study and have permission for more than one study.
- **Use HD Image.** Select **Use HD Image** to alternate between viewing the HD and normal definition backgrounds for paper CRFs. A check mark indicates that you will see HD images on paper CRFs.
- **Use Subject Alias.** Select **Use Subject Alias** to toggle between viewing the numeric Subject ID and the Subject Alias. A check mark indicates that you will see the Subject Alias. If the study definition does not include subject aliases then the displayed ID and Alias are the same.
- **Auto-Download Documents.** Toggle **Auto-Download Documents** to enable or disable the behavior of downloading attached documents *as soon as the record is visited*. Enabling this can save time when most records have attached documents and the documents will be reviewed. Otherwise, for large documents or records with many documents, auto-downloading may cause performance issues and it is better to leave this setting disabled.
- **Copy URL.** Select **Copy URL** to copy the URL of the current page to your device's clipboard. This allows you to easily share the URL with other users, and if they have permission to view the page, they are taken directly there after logging in.
- **Change Password.** Select **Change Password** to open the Change Password dialog. This allows you to update your password.
- **Build History.** Select **Build History** to open a new tab with the build history for DFweb. This allows you to review recent and past changes to DFweb and learn about any new features.
- **Logout.** Select **Logout** to exit out of DFweb and return to the login page. Remember to always Logout after completing your work.

### 2.4.2. CRF Menu

The CRF Menu is only visible on the Subject Binder page. It provides actions for the entire CRF. A file icon on the menu indicates that this CRF has documents attached. A loading spinner on the menu button indicates that the CRF documents are still loading. The following actions are available:

- **Manage Documents.** Select **Manage Documents** to open the Manage Documents dialog. This allows you to add or view documents for the current CRF. A number to the right shows the number of documents on this CRF.
- **Page History.** Select **Page History** to view the history of changes (audit trail) for the current CRF.
- **Reset Page.** Select **Reset Page** to reload the current CRF, resetting all fields and other elements to the last saved value. If you have made changes since your last save, you are warned that continuing with the reset removes unsaved changes.

## 2.5. Dialogs

### 2.5.1. Alert Dialogs

Alert dialogs provide warnings of different events or states in DFweb. Information in alert dialogs is important, and you should read them carefully before closing them. Example alert dialogs include:



- **Session Timeout Dialog.** If you have been away from DFweb for too long, DFweb logs you out. When this happens, a session timeout dialog is displayed.
- **Missing Permission Dialog.** Some actions, such as trying to directly navigate to a CRF using a URL, can result in a missing permission dialog if you do not have permission to view the study, site, subject, etc. Close this dialog to return to the closest level in the navigation that you have permission to access.
- **Data Was Modified Dialog.** Some illegal values cannot be accepted by the study server. If you save a CRF with such values, they are altered by the server, and you are notified by this dialog.

### 2.5.2. Confirmation Dialogs



DFweb displays confirmation dialogs to warn you of the (potentially unintended) consequences of an action you are about to perform and to give you a chance to cancel the action. Some confirmation dialogs are:

- **Unsaved Changes Dialog.** Resetting or navigating away from a CRF that has unsaved changes on it triggers an unsaved changes dialog. This dialog gives you a chance to stop the action and save those changes before continuing.
- **Save Plate Confirmation Dialog.** If you have entered values that cannot be saved as is by the DFdiscover server, when you save, DFweb warns you that these values may be modified, and give you a chance to go back to correct the values before saving.
- **Auto Logout Warning Dialog.** If you have been inactive in DFweb for an extended period of time, this dialog is shown with a countdown to the logout, allowing you to choose to continue your session before the countdown reaches zero.

### 2.5.3. Study Help Dialog

Click  beside the study name to open a dialog showing the study help. The content is displayed in the main body of the help dialog. Click  to close the dialog.

### 2.5.4. CRF Help Dialog

The CRF help dialog is displayed when the user clicks  beside the CRF label. Similar to the study help dialog, the CRF help dialog displays help content in the main section of the dialog, in this case, specific to the current CRF. The dialog is closed by clicking .

## 2.5.5. Modified Values Dialog

On occasion, a change in the study setup can cause a value to be saved to the study database that cannot be displayed in the field. In these cases, DFweb modifies the values as best as possible to make them fit in the field. You are notified of these modifications with this dialog when you open the CRF.

The dialog shows you a list of all fields modified in this way. For each field, the dialog shows you the field label, a message explaining why the value was modified, the value in the database, and what the value is after the modification.

Leaving the CRF without saving causes the modifications to be discarded and the database values to be preserved.

## 2.5.6. Attach Documents Dialog

The Attach Documents dialog provides a way to view and add documents to the CRF, and to download attached documents to your device. Documents are displayed in a list, and at the bottom of the list is an area for attaching a new document.

Each document in the list is displayed as a row with the document name, the size of the document, an expand document button (▼), and a download button (⬇️). Click ▼ to display the document in the dialog. Some document types cannot be displayed by the browser, so a message is shown in place of the document. Click ⬇️ to download the document to your device. This is especially useful for documents that can't be viewed in the browser as it allows you to open the document with a program designed to open files of that type.

To attach a new document to the CRF, click **Choose Files**. This opens a file chooser dialog. Select the file you wish to upload, and confirm the selection to close the dialog. Click **Upload** to attach the document.

### Note

The label of **Choose Files** may differ in the browser you are using.

If the CRF has not been saved, attaching a document saves an empty version of the CRF with the status Pending and the document attached. Saving with the CRF save button is still required to save any changes you have made to field values.


At the top right of the Attach Documents dialog is the Download All button (⬇️). This button downloads a zip file containing all the documents attached to the CRF. Click **Cancel** to close the dialog.

## 2.5.7. Change Password Dialog

The Change Password dialog is displayed when you select **Change Password** from the Application Menu, or when you login for the first time after being given a new password by the study administrator. The text of the dialog indicates minimum password requirements.

To change your password, enter a new password that matches the requirements in **New Password**. Then enter the same password again in **Confirm Password**. If the password does not meet the requirements, an error message is displayed in red below **Confirm Password**. When you have entered a password and no error messages show, click **Change** to submit the new password to the server. If the password change is not successful you are notified by an error message. Click **Cancel** to close the dialog without changing your password.

## 2.5.8. Add Subject Dialog

The Add Subject dialog is displayed when you click  from the subjects list page. It permits you to create a new subject within the range of allowable IDs for the site.

To create a new subject, enter the desired subject ID in **Enter Subject ID**. Enter the same ID in **Confirm Subject ID**. When you have entered an ID in both input areas and no errors are displayed, click **OK** to create the subject. The subject binder page for the new subject is displayed. Click **Cancel** to close the dialog without creating a new subject.

## 2.5.9. Query Dialogs

The Query Dialogs allow you to create (+), edit (\*), reply to (↩) and delete (-) queries for a field. Separate dialogs are used for each function. For a study in which multiple queries are permitted, there is an additional Multiple Queries dialog to view and initiate actions once a query has been created for the field. Click **Q** to open the query dialogs for the field. For more details on query dialogs and their use, see [Queries](#).

## 2.5.10. Reason Dialogs

The Reason Dialogs allow you to create, edit, and delete reasons for a field. Separate dialogs are used for each function. Click **R** to open the reason dialog. For more details on the reason dialog and its use, see [Add a Data Reason](#).

## 2.5.11. Missing Value Dialog

The Missing Value dialog allows you to set (or unset) a missing value for the field. Click **M** to open the Missing Value dialog. For more details on missing values and their use, see [Mark a Data Value as Missing](#).

## 2.5.12. Lookup Table Dialog

Certain edit checks may offer the opportunity to select a value from a lookup table. The behavior of lookup tables in DFweb is identical to the behavior in **DFexplore**. For further information, refer to [DFexplore User Guide, Using Lookup Tables](#).

**DFlookup: LBTEST**

@

Match ANY terms   
  Match ALL terms   
  Exactly match the term

Lookup Fields

Acronym

Result


Matched rows: 4

Acronym	Result
Bilirubin	
Bilirubin Crystals	
Direct Bilirubin	
Indirect Bilirubin	

## 2.5.13. Task List Dialog

When viewing a record as part of a task, click **View Tasks** to open the task list dialog. This dialog can be used to view the current task's details, and switch to a new task. See [Tasks](#) for more information on tasks.

## 2.5.14. Query FilterDialog

When viewing the query list, or the query binder, click  to open the query filter dialog. Update the filters to change which queries are shown. To learn more about the queries view and query filter dialog, see [Queries View](#)

## 2.5.15. Error Dialogs

On occasion DFweb may experience a problem resulting in an error dialog. This can be caused by a problem in network connectivity, the server, or DFweb itself. The dialog content gives details as to the cause of the error. Further detail regarding some errors can be found below. Depending on the error, you may be taken to a different page, or logged out, on closing the dialog.

- **Server Internal Error.** This error is caused by an issue connecting to the DFweb server. This may happen if an internet connection is unavailable, or if the DFweb server is otherwise unavailable. Closing this dialog will log you out. Check your network connection and try again. If the error persists, contact your study administrator.
- **API Error.** This error is caused by an issue connecting to the API server. This may happen if the API server is unavailable, or due to a problem in the study setup. The contents of this dialog provide more information on the nature of the issue. You may be returned to a previous page when closing this dialog.
- **Website Problem.** DFweb has crashed due to unexpected actions, input or changes in the browser. Expanding the details section reveals information useful for the DF/Net team in resolving the crash. Closing the dialog will return you to the current screen so you can copy any unsaved data. Refresh DFweb using your browser's refresh button to recover from the crash. If the crash persists, contact your study administrator, including the content of the details section.

# Chapter 3. Metadata

## 3.1. Locating Metadata

Paper CRFs and eCRFs display the **Q**, **R**, and **M** in different locations.

eCRFs display the metadata buttons for each field on the same row as the field. Since all the buttons are visible, metadata on an eCRF can be quickly and easily viewed by scrolling through the fields.

Paper CRFs only display one set of **Q**, **R**, and **M**. These are located on the right side of the window. The buttons show and allow you to alter the metadata for the field that currently has the focus. Blue, green, and orange borders on a field indicate that the field has metadata, allowing you to quickly see the metadata on a paper CRF. A red border on a field indicates that there is an error on the field.

## 3.2. Queries

Queries are used to request corrections or clarifications about the data. There are four query dialogs: Add Query, Edit Query, Reply to Query, and Delete Query. The following sections explain in detail how to use these dialogs.

For studies where multiple queries per field are enabled, there is an additional dialog where users can add a new query or choose an existing query to reply to, edit, or delete. Further details are provided in [Multiple Queries Dialog](#).

### 3.2.1. Add Query

To add a query to a field, click **Q**. If there is no query on a field, the Add Query dialog opens. Select an appropriate category from the dropdown menu, and provide the query detail in the provided text field. Once complete, click **Apply** to add a query to the field.

### 3.2.2. Edit Query

To edit a query, click **Q**. If the query is resolved, the Edit Query dialog open. Otherwise, the Reply to Query dialog opens. Click **Edit**, and the Edit Query dialog opens. Select an appropriate category and status from the dropdown menu, and provide the query detail in the provided text field. Once complete, click **Apply** to finish editing the query.

### 3.2.3. Reply to Query

If a query is already resolved, it cannot be replied to. Otherwise, to reply to an outstanding query on a field, click **Q**. The Reply to Query dialog opens, displaying the query detail. Enter the query reply content in the provided text field. Once complete, click **Apply**.

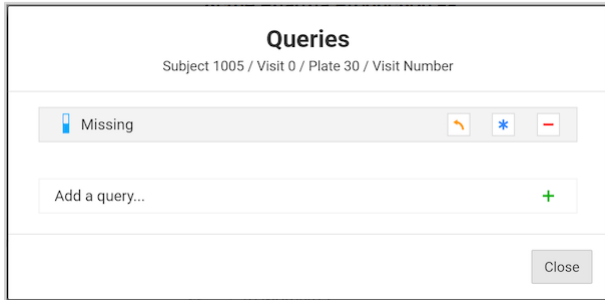
### 3.2.4. Delete Query

Queries are rarely deleted. Once a query is created, it should be resolved, perhaps as irrelevant.

If it is necessary to delete an existing query, click **Q**. If the query is outstanding or pending, the Reply to Query dialog opens. Click **Edit**, and the Edit Query dialog opens. Click **Delete**, the Delete Query dialog opens. In the Delete Query dialog, click **Delete** to finish deleting the query on the field. At each step please ensure that the query really should be deleted.

### 3.2.5. Multiple Queries Dialog

In a study with multiple queries per field enabled, click **Q** for a field with an existing query to see the following multiple queries dialog:



The icons used in the multiple queries dialog are:

-  Reply
-  Edit
-  Delete
-  Add

Additionally, there is another difference between single and multiple query-enabled study query dialogs. In single query-enabled studies there are navigation buttons at the bottom of the dialogs to get from one dialog to another. These aren't present on multiple query-enabled study query dialogs. Instead, the multiple query-enabled study query dialogs have a back arrow at the left top corner. The back arrow returns you to the Multiple Queries dialog.

## 3.3. Add a Data Reason

Reasons are a way to provide additional information about existing data or to explain why data is changed. For each data field, the user can add a new reason or edit an existing reason using the Reason for Data Value dialog.

To add a reason to a field, click **R** next to the field. The Reason for Data Value dialog opens. Select an appropriate status from the dropdown menu and enter reason detail in the provided text field. Click **Apply** to add the reason to the field.

In some cases, the Reason for Data Value dialog may open automatically when a data value is changed. In these cases, a reason is required before the data change is accepted. If the data change was made in error, click **Revert to Old** in the Add Reason dialog to discard the data change.

To edit an existing reason, click **R** to open the Reason for Data Value dialog. Change the reason status and/or detail and click **Apply** to finish editing and close the dialog.

To delete an existing reason, click **R** to open the Reason for Data Value dialog. Click **Delete** and then click **Confirm Delete** to confirm that the reason should be deleted.

## 3.4. Mark a Data Value as Missing

Missing value codes provide a way to mark a data value as missing. Users may select a missing value for any data field that is not essential to indicate that the data value will not be entered.

To mark a data value as missing, click **M** next to the input field. The Missing Value dialog opens. Select an appropriate missing value from the dropdown menu, and click **Apply** to finish.

After marking a data value as missing, the field value is set to the missing value code and the field is disabled. Disabled fields can still be tabbed to, however editing the field is not possible.

To enter data in a field that has been marked as missing, click **M** next to it. In the Missing Value dialog, select the **No Code (Reset)** option from the dropdown menu, and click **Apply** to finish. This enables the field for data entry and resets the field value to blank. **No Code (Reset)** can also be used at any time to clear a data value currently on that field.

## 3.5. Resolving Queries

Queries can be resolved via **Q** on the field.

Click **Q**, and then click **Edit** for the query that is to be resolved. Select an appropriate Status from the dropdown menu, and add Detail and Note in the provided text areas as needed. Once complete, click **Apply** to resolve the query.

## 3.6. Managing Documents

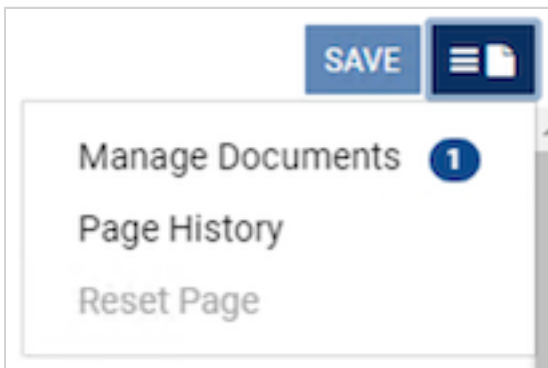
DFweb allows users to attach documents to a plate, which accommodates adding more data and information in other formats.

### 3.6.1. Supported Document Types

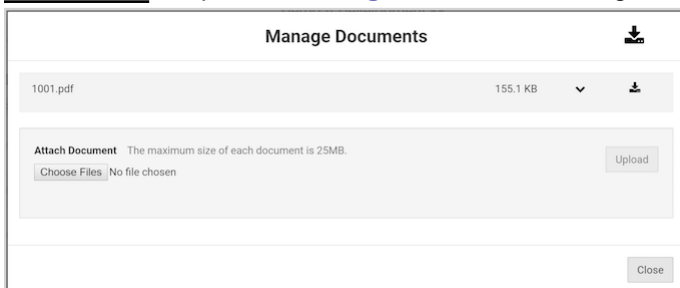
DFweb allows user to upload, view and download PDFs, images, audio, and video. Specifically for images, DFweb supports JPG, JPEG, PNG, BMP, DICOM, DIC, and DCM format; for audio, DFweb supports MP3, and WAV format; for video, DFweb supports MP4, and AVI format. The file size limit is 25 MB.

### 3.6.2. Reviewing Documents

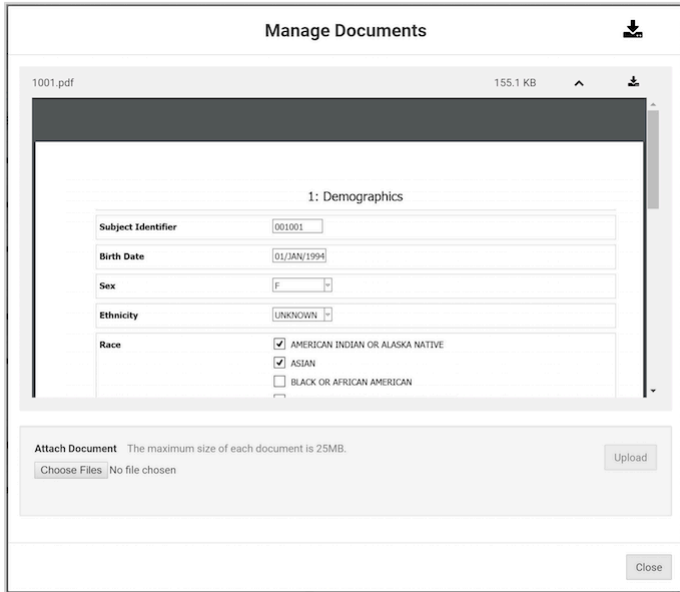
Navigate to the **Manage Documents** dialog to review documents. This is available via the Manage Documents menu item under the CRF Menu **☰** (without documents) or **☰** (with documents), in the top right corner of the plate. Click **☰** to choose from the dropdown menu items:



The number next to **Manage Documents** indicates the number of existing documents for this plate. Click **Manage Documents** to open the **Manage Documents** dialog. Below is an example of the **Manage Documents** dialog.



In the **Manage Documents** dialog, users can review documents. To review a document, click **▼** to expand the collapsible content:



Click  to collapse the content.

Many document types can be previewed or played without downloading first, including PDF, JPG, JPEG, PNG, BMP, MP3, WAV, and MP4 format. For DICOM, DIC, DCM, AVI or other formats, they must be downloaded first.



### 3.6.3. Adding Documents

Navigate to the [Manage Documents](#) dialog by following the instructions in [Reviewing Documents](#).

Click [Choose Files](#) to open the file browser and select one or more files from your computer. Once complete, click [Upload](#) to add the file(s).

### 3.6.4. Downloading Documents

Navigate to [Manage Documents](#) dialog by following the instructions in [Reviewing Documents](#).

Click  to the right of the file name to download that particular file. Click the large  at the top of the dialog next to the Manage Documents title to download in a zip file all the documents listed.

## 3.7. Sharing Links

The ability to share links minimizes the time and effort to navigate to a particular page.

Click the Application Menu, , and then select [Copy URL](#) from the dropdown menu. The copied URL can be re-visited at a future time, or shared with others.

When using a copied URL, the user is redirected to the login page first, where they are required to login. After successful login, the user is taken to the linked page.

# Chapter 4. Queries View

## 4.1. Opening Queries View

Queries View allows you to review data queries, with filter options such as query status (outstanding, pending, resolved), query category (such as missing, illegal, overdue visit), and query timing.

### Note

Query View is only available when **DFweb** is connected to DFdiscover server and API version 5.5 or later.

Once you have selected a study, the list of data queries is available by clicking **Queries** in the sidebar on the left of the screen.

Location	Query Header	Query Details	Timing
350001 Screening DM: Demographics	Sex = 2 (Inconsistent) Outstanding	Detail: Tadas Testing Time	Modified by: eric Apr 25, 2018 11:56:20
350001 Month 8 SE: Subject Encounter	3a. Bottle # = 29 (Illegal) Outstanding	Detail: The value entered (29) is outside of the expected Legal Range (1-15). Please review.	Modified by: clare May 30, 2018 11:42:55
350003 Month 1 VS: Vital Signs	Systolic Blood Pressure Result 1 = 065 (Illegal) Outstanding	Detail: The value entered (65) is outside of the expected Legal Range (70-180). Please review.	Modified by: clare Nov 09, 2017 13:35:50
350003	SDV Check =	Detail: SDC Review Required	Modified by: demo_user1 Apr 23,

By default, the outstanding queries from the first site in the site list are shown. If you open a site before clicking queries in the sidebar, the queries for that site will be shown by default. Both the site and status can be changed using the filters.


With the query list open, a table of queries with 4 columns is shown. The columns of the table are:

- **Location.** Shows the subject ID, visit label and label of the CRF the query is on. Also shows the status of the query as an icon.
- **Query Header.** Shows the field name, field value, category, and status of the query in the format of "Field name = Field value (Category)" with the status on the next line.
- **Query Details.** Shows the query details, any reply that was given to the query, and any notes added to the query.
- **Timing.** Shows when the query was created and last modified, and by whom it was created and last modified.

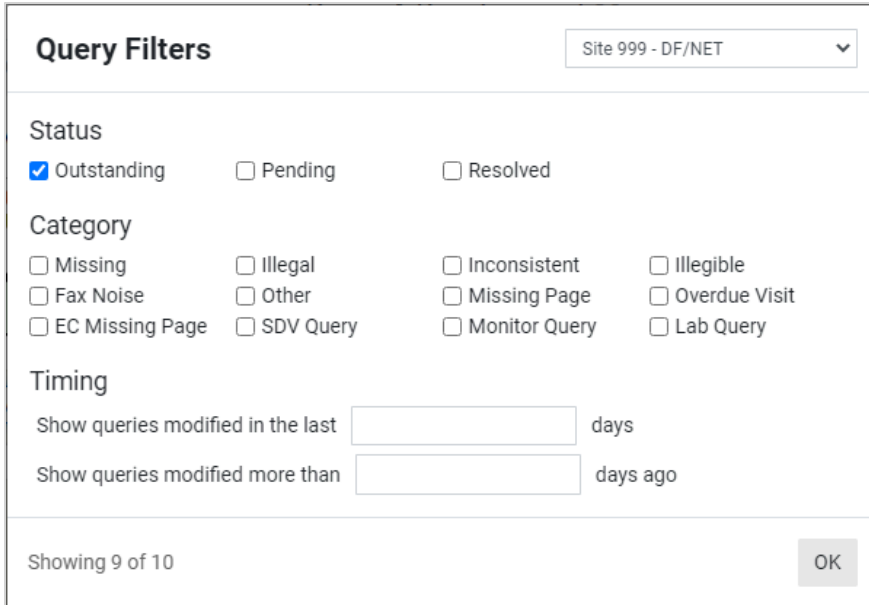
### 4.1.1. Filtering the Query List

In addition to the queries list, the Queries page also includes options to filter queries by site, status, category, and timing. The number of queries matching the filter and the total queries in the site is shown next to the filters.

The site, status and category filters are can be changed quickly using the dropdowns on the query list page. Selecting a value from these will update the table to show only the queries that match the new filter. The status and category filters


also have an Any option, which removes the filter and shows queries with any of those options. Click  to open filter dialog for more filtering options.

### 4.1.1.1. Query Filter Dialog



The query filter dialog provides access to the same filters as in the query list page, plus the timing filters. In the dialog, it is possible to select more than one status or category so queries with any of the selected options show. Updates to the site, status, and category filters in the filter dialog also update the dropdowns on the query list page. If more than one option is selected for status or query, then the corresponding dropdown on the query list page will display **Multiple Statuses** or **Multiple Categories**.

The timing options allow you to filter by queries modified before or after a certain number of days ago. Adding a value to one of the timing fields will clear the other.

Once you have the desired filters applied, click  to return to the query list page.


### 4.1.2. Sorting the Query List

The query list is sorted based on the subject ID, visit number and CRF number in ascending order by default. This can be reversed to show the highest subject ID, visit and CRF first by clicking the Location column header. In addition, it is possible to sort the queries based on when they were last modified by clicking the Timing header. Clicking again reverses the direction of the timing sort as well.

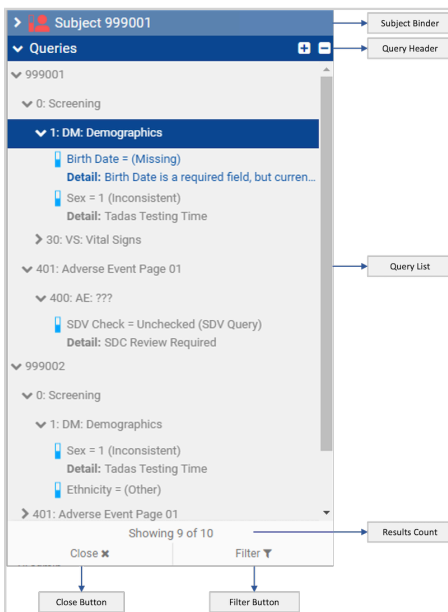
### 4.1.3. Reviewing a Query

To open the CRF that contains a query, double-click anywhere on the query row.

## 4.2. Reviewing Queries

To review a query, double-click any query to open the CRF and go to the field where the query is located. Click  to open the query dialog.

The query binder is opened in the sidebar with the current subject, visit, CRF and query showing. All filters applied to the query list in the query list page are also applied to the query binder. You can review, filter and navigate through the query list using the query binder.



- **Subject Binder.** View all CRFs in the current subject binder by clicking the subject binder header. Clicking again collapses the subject binder and reopens the query binder.
- **Query Header.** Click the query binder header to collapse or expand the query binder. Click  to expand all subjects, visits, and CRFs so all queries are shown in the list. Click  to collapse them all so all queries are hidden.
- **Query List.** The query list shows the status icon, field name, field value, category, detail and reply of all queries. Click a subject, visit or CRF to expand or collapse it. Click a query to navigate to that CRF and field. Hovering over a query in the query list shows more details about the query.
- **Results Count.** Shows the number of queries that match the filter criteria, and the total queries in the currently selected site.
- **Close Button.** Closes the query binder while staying on the current CRF.
- **Filter Button.** Opens the [Query Filter Dialog](#).

The query binder stays up to date with the data that has been saved. If you make a change to a query, you must save it for the changes to appear in the query binder.

### 4.2.1. Reviewing Other CRFs

You can expand the subject binder to view all other CRFs in the subject binder for the current subject. You can open CRFs from the subject that don't have queries in the query binder to review their contents and assist you in reviewing a query. Expand the query binder and click the query you were working on to return to the query.

### 4.2.2. Filtering the Query Binder

Click  in the sidebar to open the filter dialog. The filter dialog behaves the same as when opened from the query list, but it updates the query binder instead. See [Query Filter Dialog](#) for more details.

### 4.2.3. Closing the Query Binder

Click  to end the task you are working on. You will stay on the current CRF, but the query binder will be closed.

# Chapter 5. Tasks

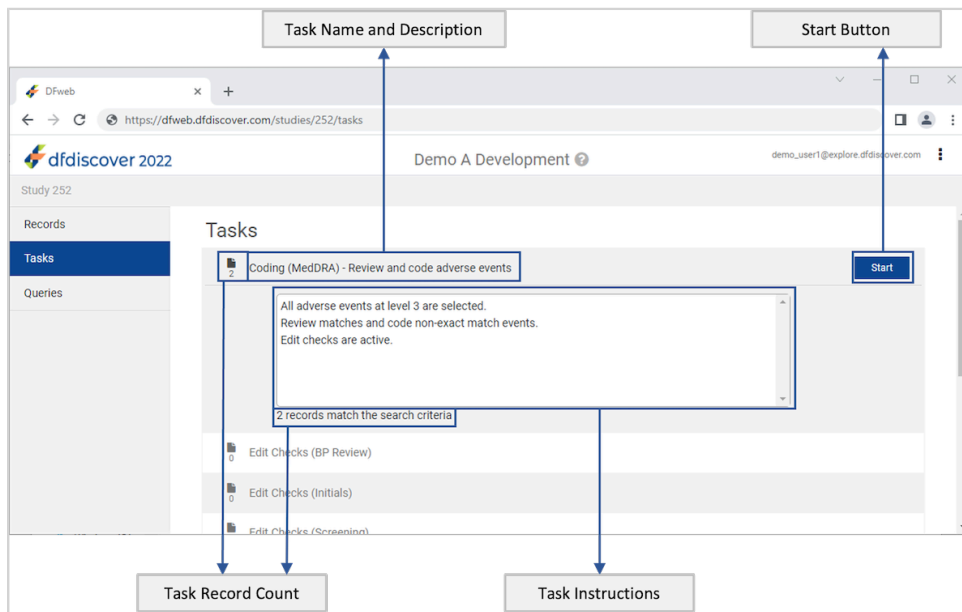
## 5.1. Task Listing

Tasks is a feature that allows you to retrieve a set of CRFs to review. Each task has its own purpose, defined by the study sponsor or coordinating center, and may include instructions.

### Note

Tasks are only available when **DFweb** is connected to DFdiscover server and API version 5.5 or later.

Once you have selected a study, the list of tasks will be available by clicking **Tasks** in the sidebar on the left of the screen.



On the task list page, the headers of all the tasks available to your role are shown, and the first task is expanded to show more details.

The task header shows:

- **Task CRF Count.** Indicates the number of CRFs currently in this task.
- **Task Name and Description.** The name of the task is shown in the header, followed by a dash and then the description of the task, if it has one.
- **Start Button.** For the currently expanded task, **Start** is shown in the task header.

Clicking the header of a task expands the task and closes any previously expanded task. Once expanded, the task details show:

- **Task Instructions.** Instructions provided for the task, if any.
- **Task CRF Count.** The number of CRFs currently in the task.

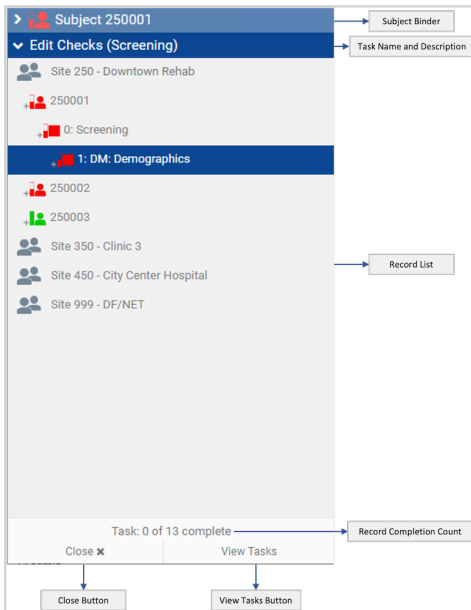
If a task has a CRF count of zero, the Task Name and Description and Task CRF Count are de-emphasized, and **Start** is disabled. You cannot start a task with no CRFs.

## 5.1.1. Starting a task

To start a task, expand the task you wish to work on, then click **Start**. This will open the CRF view and take you to the first CRF in the task.

## 5.2. Task Results

Starting a task takes you to the data entry form with the task binder open in the left-hand sidebar. The first CRF according to site, subject, visit and CRF number is opened, and the other CRFs in the task are available in the task binder sidebar.



The task binder sidebar shows:

- **Subject Binder.** View all CRFs in the current subject binder by clicking the subject binder header. Clicking again collapses the subject binder and reopens the task binder.
- **Task Name and Description.** The name of the task is shown in the task binder header, followed by a dash and then the description of the task, if it has one. Click the task binder header to collapse or expand the task binder.
- **CRF List.** All CRFs in the task are shown in this CRF list. The CRFs are organized by site, subject, and visit.
- **CRF Completion Count.** The CRF completion count shows the completed and total number of CRFs in the task.
- **Close Button.** Click **Close** to stop working on the task while keeping the CRF open.
- **View Tasks Button.** Open a dialog showing the current task details, and a list of other available tasks.

Following the instructions for the task, complete the necessary changes on the CRF. Saving the CRF updates the CRF completion count and marks the CRF with a checkmark in the sidebar to show that it was completed. Click on the next CRF, visit, subject or site move to the next CRF in the task.

### 5.2.1. Reviewing Other CRFs

You can expand the subject binder to view all other CRFs in the subject binder of the current subject. You can open CRFs from the subject that aren't in the task to review their contents and assist you in completing the task. Expand the task binder and click the task CRF you were working on to return to the task.

## 5.2.2. Switching Tasks

Click **View Tasks** to open a dialog with the list of tasks available. The current task is expanded by default. Select the task you wish to switch to, and click **Change Task** to change tasks. The first CRF in the selected task will be opened. The state of the current task is not preserved when you switch, so the completed CRFs will be reset if you switch back to the first task.

## 5.2.3. Closing a Task

Click **Close** to end the task you are working on. You will stay on the current CRF, but the task binder will be closed.

Returning to the site, subject, or study list pages also ends the task. You can restart the task you were on from the task list page.

# Appendix A. Copyrights - Acknowledgments

## A.1. External Software Copyrights

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### A.1.1. DCMTK software package

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This software and supporting documentation were developed by

OFFIS e.V.

R&D Division Health  
Eschereg 2  
26121 Oldenburg, Germany

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### **A.1.5. mpack/munpack**

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## A.1.7. PostgreSQL

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## **A.1.16. d3.js**

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