

DFcollect User Guide

DFcollect User Guide

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Abstract

This guide describes the DFcollect app.

The instructions are intended to describe, in general terms, how data entry tasks are performed using DFcollect. 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

DFcollect is a tablet-based app for data collection in support of a DFdiscover study.

1. Getting Help

For software support, please contact the DFdiscover team:

- via email, <help@dfnetresearch.com>;
- visit our website, 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 DFcollect?

DFcollect is a tablet-based mobile application that allows users to perform online and offline data collection for a DFdiscover study.

DFcollect is distributed on Google Play™ for Android™ devices and the Apple® App Store® for iOS® devices.

1.2. Compatible Devices

DFcollect requires a device running Android™ 5.1 or greater, or iOS® 11 or greater. The user interface is optimized for tablets. The minimum screen resolution is 800 x 600 and the minimum memory requirement is 2GB. The device must have Wi-Fi and/or cellular communication capabilities.

1.3. Capabilities

The main purpose of DFcollect is to facilitate data collection using a mobile device at clinical sites participating in a DFdiscover study. For users that need to collect clean data, in online and offline settings, and do not need the extended feature set of **DFexplore**, **DFcollect** is the perfect tool.

DFcollect includes several data validation features including legal range checking, type validation, required values, field skipping, missing value coding, and edit checks, plus several metadata features, including adding, resolving, and editing queries, and adding reasons for data values. Management of study documents related to clinical subjects is also available.

1.4. General Terminology & Interface Elements

DFcollect includes several key pages, menus, and dialogs to facilitate data entry. These pages are explained here, and the terminology used in this document and DFcollect is defined. More detailed explanations of key screens and functionality are given in the following sections.

1.4.1. Main Application Pages

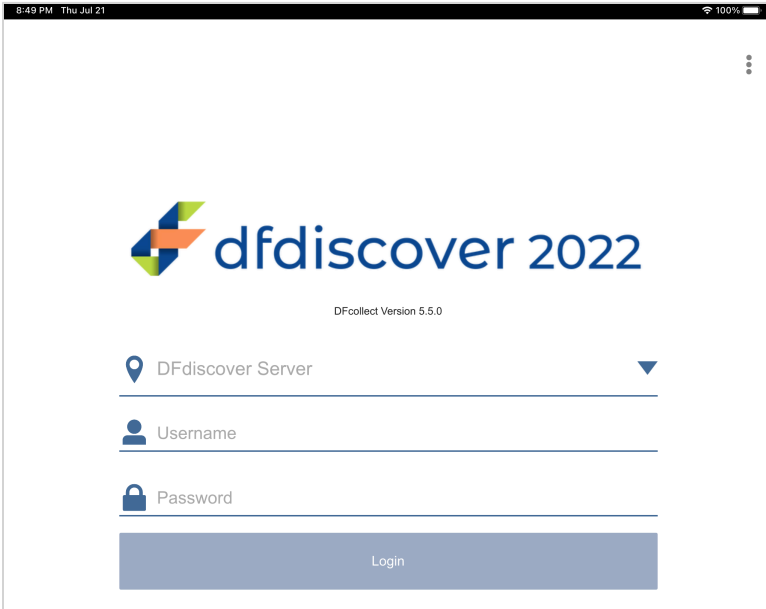
DFcollect is an installed app. DFcollect is available on Google Play™ and Apple® App Store®. It must be downloaded and installed before use.



Once installed on your device, DFcollect has the following appearance:

1.4.1.1. Login Page

DFcollect is distributed on Google Play™ for Android™ devices and the Apple® App Store® for iOS® devices. Once DFcollect is installed on the device, select the app icon to open DFcollect. The login page is the initial landing page in DFcollect.



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 DFcollect 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.

Note

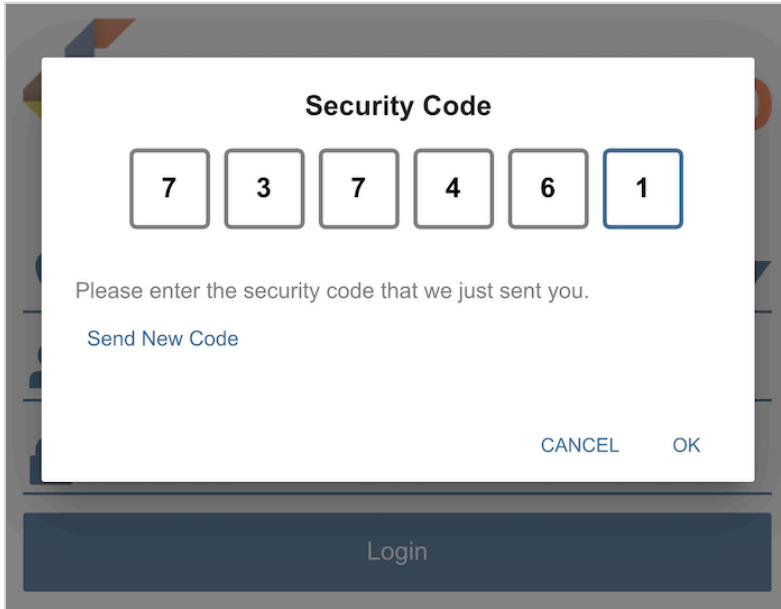
For security purposes, your account will be locked if you enter an incorrect username and password 5 times in a row while offline. To unlock your account, you must be online. Log in with your correct username and password, or use the Forgot Password option to reset your password.

If you don't remember your password, choose **Forgot Password** from the **Application Menu**. 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.

1.4.1.1.1. 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.



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 to complete login.

1.4.1.1.2. Logging Out

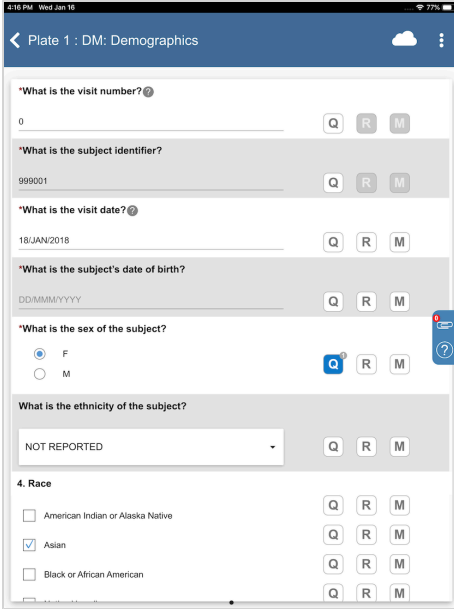
To exit from DFcollect, choose **Logout** from the [Application Menu](#). After successful logout, the login window is shown.

When using DFcollect, logging out via **Logout** in the [Application Menu](#) is the recommended and most secure way to exit DFcollect. Although closing the app ensures your data is safe, it does not imply that unsaved data changes have been applied to the database (or can be recovered). It is best practice to always logout properly.¹

1.4.1.2. Overall Application Appearance

In addition to the login page, there are several intermediate pages. These pages allow the user to select a study, site, visit, and finally a CRF for data entry.

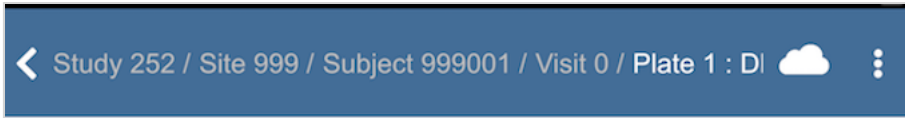
¹ The native Android™ action of swiping an app from the list of currently running apps (overview button) is interpreted in DFcollect as a logout action. The behavior in the iOS® app switcher is not consistent and may change across iOS® versions - do not rely upon closing DFcollect via the app switcher to apply unsaved changes or logout correctly. action.





The main application page is the primary interface for most data entry tasks. This page has the following features:

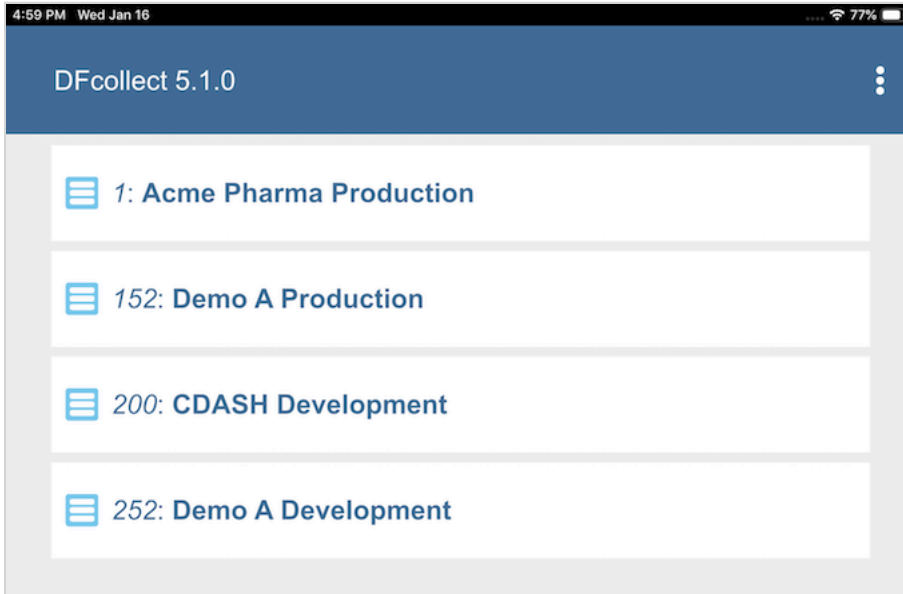
- **Header Panel.** The header panel is available on all pages of DFcollect except the login page. It contains options and navigation that are relevant for the current page, including:

Figure 1.1. Header Panel




- **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.
- **Application Menu.** The application menu, accessed by clicking  or , contains several generic functions that are not study specific, including **Storage & Syncing**, **Change Password**, **Query View**, **Task Listing**, and **Logout**. See [Application Menu](#) for more information.
- **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](#), [Subject Binder](#), and [Data Entry Form](#).

1.4.1.3. Studies Page



The Studies Page is the first page you navigate to after successful login. It lists the studies you have permissions for. Click one of the available studies to choose that 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 number, name, and status are displayed on each line. If the study is not available, the icon will be displayed as . Click the study name to show the reason that the study is not available.

1.4.1.4. Sites Page

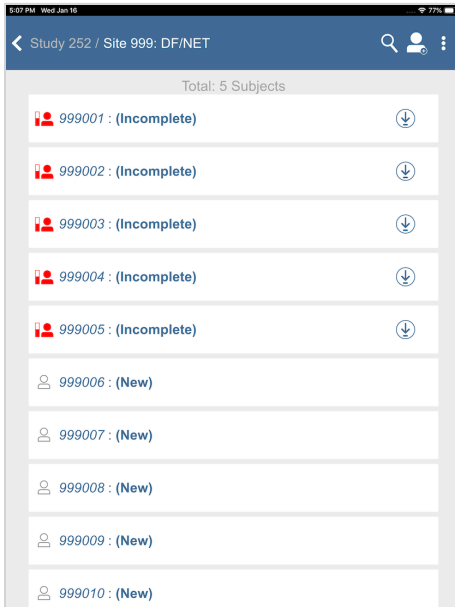


The Sites Page contains a list of the sites you have permission for. The site number and label are shown, one per row. Click one of the sites to make it the active site. This takes you to the Subjects Page for that site.





The Sites page also includes search functionality. Click  to display the search field, enter the search term, and click  again to see the results. Use  and  to navigate between multiple search results. Select  to return to the top of the page.

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







1.4.1.5. Subjects Page



The Subjects Page contains a list of permitted subjects. Click a subject to go to 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.

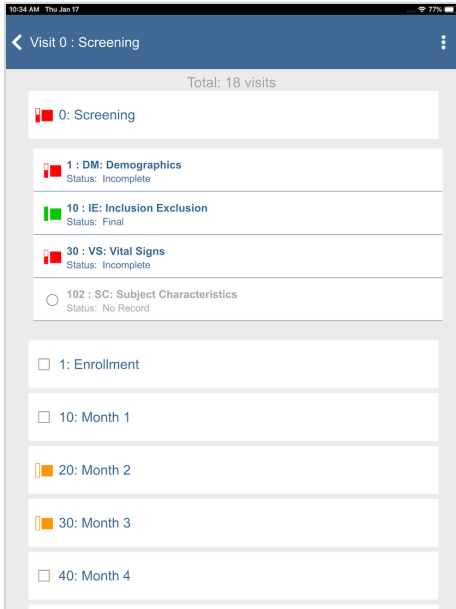
-  The subject binder is final, all data required at this time has been submitted, and there are no outstanding responses or missing, required values.
-  The subject binder is incomplete. There may be missing, required values, illegal values or unresolved questions about the data.
-  The subject binder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

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. Click  to display the search field, enter the subject ID to search for, and click  again to see the results. Use  and  to navigate between multiple search results. Select  to return to the top of the page.
- **Add Subject.** Click  to open the [Add Subject Dialog](#).

1.4.1.6. Subject Binder












The Subject Binder contains all of the visit and CRF information related to the current subject. Further details regarding the Subject Binder can be found in [Chapter 2, Data Entry](#) and [Chapter 3, Metadata](#). An overview is provided here.



The subject binder displays the list of visits and CRFs for the selected subject. The breadcrumb at the top of the screen displays the study number, site number, and subject ID. The main body of the page displays, for the subject ID, all of the visits that you have permission to view.

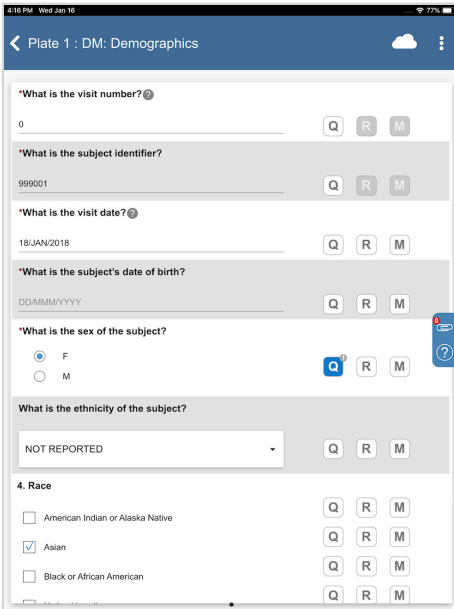
Click any visit to expand it and show all the CRFs in that visit that you have permission to view. CRFs are indented slightly from the visits and shown in a smaller font to help visually differentiate them. CRF and visit labels follow the format [Number]: [Label].

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 open the CRF, or click a different visit to display the available CRFs for that visit.

1.4.1.7. Data Entry 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 value codes, view and add documents to the CRF, and view available CRF help.


Figure 1.2. Data Entry Form Header



At the top of the form is a header area for CRF and study actions. The header remains visible as you scroll through the CRF contents. It contains:

- **CRF Label.** The CRF label is composed of the CRF number and label. These follow the format [Number]: [Label]. The CRF label also functions as a breadcrumb. Swipe right to see the study, site, subject, and visit for the CRF, and click on any part to navigate back to that page.
- **Save Button.** The appearance of the Save button changes depending on the connection status of the app (online/offline) and whether changes have been made to the CRF:
 - - This CRF has not changed, and the app is online.
 - - This CRF has changed and is not yet saved, and the app is online. Click to save changes to the database.
 - - This CRF has changed and is not yet saved, and the app is offline. Click to save changes locally. See [Working Offline](#) for further details.
 - - The CRF changes have been saved successfully to the study database.
 - - The CRF changes have been saved successfully to local storage, while offline. The changes must still be uploaded to the study database once back online.

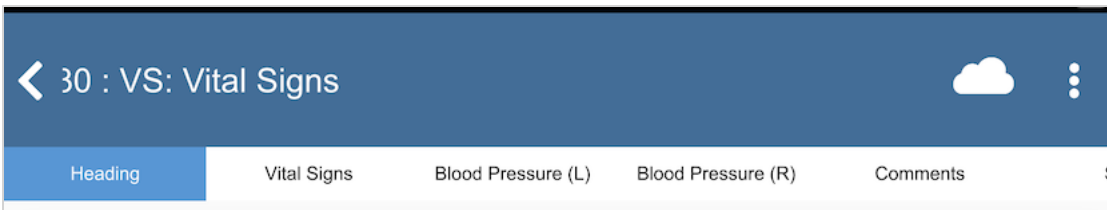
-  - This CRF is read only; it may be locked by another user or editing may not be permitted.
-  - This CRF is read only based on user permissions.

Click  to save the changes you have made to the current CRF and submit them to the server.

- **Application Menu Button.** Click  to open the [Application Menu](#), which contains study level options.

The remainder of the form contains the data entry area of the CRF. For CRFs using screens, they appear as tabs across the top of the data entry form.

Figure 1.3. Data Entry Screens









Click the corresponding tab to go to that screen, or swipe left to go to the next screen and swipe right to go to the previous screen.

The screenshot shows a data entry form with several fields, each with a 'Q', 'R', or 'M' icon to its right. The fields are:

- 'What is the visit number?' with input '0'.
- 'What is the subject identifier?' with input '999001'.
- 'What is the visit date?' with input '18/JAN/2018'.
- 'What is the subject's date of birth?' with input 'DD/MM/YYYY'.
- 'What is the sex of the subject?' with radio buttons for 'F' (selected) and 'M'.
- 'What is the ethnicity of the subject?' with a dropdown menu showing 'NOT REPORTED'.
- '4. Race' with checkboxes for 'American Indian or Alaska Native', 'Asian' (checked), and 'Black or African American'.

Each screen is composed of rows of fields. Rows are shaded with alternating color backgrounds. Each field can contain:



- **Field Label.** The field label shows the field prompt, if it is available. Otherwise the field description is used for the label.
- **Field Input.** Each field has an input area. The data type and format of the field 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 equivalent to typing it in the Field Input.

- **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.
- **Field Help.** If there is help information for the field,  is visible. Click to display a help tooltip, which can be dismissed by clicking any other area of the page.
- **Required Indicator.** If the field is required or essential,  appears on the line. Fields with this indicator display a warning message if left blank.
- **Metadata Indicators.** , , and  are displayed on each line. They allow the user to add, modify and view queries, reasons and missing value codes for that field. For more information on queries, reasons, and missing value codes, see [Chapter 3, Metadata](#).
- **Focus Indicator.** A colored vertical bar indicates that the field is in focus, and the color indicates the status of the field. To learn more, see [Focus Indicators](#).
- **Warning Message.** Warning messages appear when issues like illegal field values are present in the field. Correct the issue to remove the message.

On each data entry screen, the CRF Menu is positioned on the right side of the display, vertically centered. It provides options to view and upload documents and to view CRF help. See [Section 1.4.2.2, “CRF Menu”](#) for further details.

1.4.2. Menus



1.4.2.1. Application Menu

The application menu provides functionality applicable for the entire study or user session. Click  or  to access the application menu. The following options are available:

- **Preferences.** Select [Preferences](#) to view and modify user and system settings. See [Preferences](#) for further details. This preference is only available after logging in.
- **About DFcollect.** Select [About DFcollect](#) to view the version and build information about DFcollect.
- **Forgot Password.** Select [Forgot Password](#) to request a password reset. This option is only available before logging in and while online.
- **Change Password.** Select [Change Password](#) to change your password. See [Change Password](#) for further details. This preference is only available after logging in and while online.
- **Task Listing.** Select [Task Listing](#) to view and open data tasks available for you. See [Tasks](#) for further details.
- **Query View.** Select [Query View](#) to review the list of outstanding, pending, and resolved data queries. See [Query View](#) for further details.
- **Storage & Syncing.** Select [Storage & Syncing](#) to view and manage records stored locally (for offline use) and to upload data saved while offline. See [Working Offline](#) for further details.
- **Study Help.** Select [Study Help](#) to open a dialog with the help information defined for the study.
- **Reset.** Select [Reset](#) to remove all local data and settings for the login user. If there is locally stored study data that has not been synced, a warning confirmation is presented first. This action is recommended if use of the device by a user has ended.
- **Logout.** Select [Logout](#) to exit the current study and return to the login page. Remember to always logout after completing your work.

1.4.2.2. CRF Menu

The CRF Menu is visible only on the data entry form. It provides actions for the selected CRF. The following actions are available:

- **Manage Documents.** Select  to open the Manage Documents dialog. This allows you to add or view documents for the current CRF. The number in red is the number of documents attached to this CRF. See [Managing Documents](#) for further details.
- **Page Help.** Select  to open the help information for this CRF.

1.4.3. Dialogs

1.4.3.1. Alert and Confirmation Dialogs

Alert dialogs provide warnings of different events or states in DFcollect. Confirmation dialogs warn you of the (potentially unintended) consequences of an action you are about to perform and give you a option to cancel the action. Information in alert and confirmation dialogs is important, and you should read them carefully before closing them. Example dialogs include:

- **Error Dialogs.** Error dialogs warn you of errors in DFcollect. These could be caused by a problem connecting to the DFdiscover server, or errors in DFcollect's functionality. The text in the dialog provides details as to what happened. Depending on the error, DFcollect may return to another page, logout, or stay on the current page.
- **Unsaved Changes Dialog.** Navigating away from a CRF that has unsaved changes triggers an unsaved changes dialog. This dialog gives you a chance to stop the action and save those changes before continuing.
- **Session Timeout Dialog.** If you have been away from DFcollect for too long, DFcollect logs you out. When this happens, a session timeout dialog is displayed. To continue you must login again.

1.4.3.2. Modified Values Dialog


On occasion, a change in the study setup can cause a value to be saved to the study database that can no longer be displayed in the field. In these cases, DFcollect 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.

| Modified Values | | | |
|---|--|----------------|----------------|
| The following fields on this plate contain impossible values based upon the current field definition. The values have been modified as indicated below. Leaving the plate without saving will allow you to discard these changes. | | | |
| Field | Problem | Original Value | Modified Value |
| What is the subject's date of birth? | Date fields must either match the format length or be empty. The format length is 11 | //1964 | (none) |

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.

1.4.3.3. Add Subject Dialog


The Add Subject dialog is displayed after you click  on the Subjects Page. Use it to start data entry for a subject ID that does not appear in the list. The subject ID must be within the defined legal range 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.


1.4.3.4. 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. Your permissions may not grant you access to all of the functions. For a study in which multiple queries are permitted per field, there is an additional Multiple Queries dialog to view and initiate actions once a query has been created for the field. Click  to open the query dialogs for the field. For more details on query dialogs and their use, see [Queries](#).

1.4.3.5. Reason Dialogs

The Reason Dialogs allow you to create, edit, and delete reasons for a field. Your permissions may not grant you access to all of the functions. Separate dialogs are used for each function. Click  on the field's row to open the reason dialog. For more details on the reason dialog and its use, see [Add a Data Reason](#).

1.4.3.6. Missing Value Code Dialog



A Missing Value Code is a standard way to record that there is no response for a field and code the reason why. The Missing Value Code dialog allows you to set (or unset) a missing value code for the field. Click  to open the Missing Value Code dialog. For more details on missing value codes and their use, see [Mark a Data Value as Missing](#).

1.4.4. Terminology



A glossary of frequently used terms is presented below.

| | |
|----------------------------|---|
| Document | A document is a file that is, or will be, attached to a CRF. Documents can be images, PDFs, videos or other file types. |
| Field | A field is a single data value and optional related metadata, including queries, the reason for the data value, possibly a missing value code, and other descriptive information about the field, such as its label and help. In DFcollect, fields are presented as rows in screens. |
| Final (Status) | 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. DFcollect marks Final records with a green shaded rectangle (see also Incomplete and Pending). |
| Incomplete (Status) | 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. DFcollect marks Incomplete records with a red partially shaded rectangle (see also Final and Pending). |
| Missing Value Code | A missing value code is used to identify a field that is known and accepted as empty. Used proactively, a missing value code can reduce the need for a query and explanation for a blank field. A missing value code allows even a required field to be blank and for the CRF to still be saved as Final. |
| New (Status) | 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. DFcollect marks new records by an empty grey square, circle, or subject icon without a rectangle.

| | |
|-------------------------|--|
| Pending (Status) | DFcollect saves CRFs as Pending after a document has been added to a new CRF but no data entry has been done. DFcollect marks pending records with an orange empty rectangle. |
| Plate, or CRF | 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 on one or more screens. Each CRF may stand alone, or CRFs may be grouped into multi-CRF forms. A collection of CRFs (or forms) constitute a visit, and a collection of visits constitute the subject binder, which holds all study data for an individual subject. |
| Query | 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 request a correction or clarification. A query is metadata about the data value, or lack thereof, in the field. DFcollect 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. |
| Reason | 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. DFcollect 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. |
| Save | None of the changes made to a CRF are saved to the study database (if online) or to local storage (if offline) until you save the changes using  or  . If you leave your device without saving your work, DFcollect will time out after a few minutes and any unsaved changes will be lost. |
| Screen | 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. DFcollect indicates screens using tabs at the top of the data entry form. Select the appropriate tab or swipe to move between screens. |
| Subject | 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. |
| Subject Binder | A subject binder contains all of the required and optional data collection forms used to collect study data for an individual subject. Within DFcollect, 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. |
| Visit | 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 subject's participation in a study is often marked by a baseline visit, several repeating visits, and a termination visit. |

1.5. Preferences

Click  or  and select **Preferences** to view and modify user and system settings.

Preference changes are limited to the current device and user.

Preferences

User Settings

Exit After 10 minutes of inactivity

Read Only

Download Documents

System Settings

API Server dfws.dfdiscover.com

Server Connection

CLOSE

The following preferences can be modified:

- **Exit After ... minutes of activity.** This setting defines the amount of time DFcollect will remain inactive before the user is automatically logged out. Note that the actual logout timer interval may be longer than indicated on some devices (e.g. slower CPUs, older tablets). In most environments, a value between 10 and 20 minutes is optimal.
- **Read Only.** Enable this setting to ensure all data and metadata is available read only, and cannot be written. No changes to CRFs, queries, reasons, missing values, or documents can be made in DFcollect with this setting turned on. This is a useful setting for a reviewer who does not have modify permissions and wants to ensure that they do not make changes inadvertently.
- **Download Documents.** Enable this preference to include documents when downloading subject data for offline use. You may wish to disable this preference if you have limited storage space on your device. For further details, see [Working Offline](#).
- **Use Subject Alias.** Select Use Subject Alias to alternate between viewing the numeric Subject ID and the Subject Alias. If enabled you will see the Subject Alias; if not enabled, you will see the Subject ID, the default. If the study definition does not include subject aliases then the displayed ID and Alias are the same.
- **API Server.** The API server name may be updated from the default, if required for your study as advised by the study coordinating site. The value is a fully qualified domain name, which may optionally be followed by a port number. This preference is only settable *before* logging in. Once set as instructed by the study coordinating site, you will not need to change this value.
- **Offline Only.** Enable this preference to login without connecting to the server (i.e. remain offline) even if you are connected to the internet. This is a proactive choice that is recommended if you will be offline or in a setting where connectivity is not stable. This preference is only settable *before* logging in.

- **Language.** Set the language for the interface. The available languages are English and French. As additional languages are supported, they will appear in the drop-down list.


1.6. Change Password

To change your password, click  and select **Change Password**. The Change Password dialog opens, indicating the minimum password requirements. Enter a new password in **New Password**, then enter the same password again in **Confirm Password**.

If the password does not meet the requirements or the confirmed password does not match, an error message is displayed in red. Once any errors are resolved, select **Change** to save the new password. If the change does not succeed, an error message describes the problem. To close the dialog without changing your password, select **Cancel**.

1.7. Locking

When you open a CRF while online, DFcollect attempts to establish a lock on the CRF. If it succeeds, you gain the lock on the CRF and other DFdiscover users and apps will not 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  in the header. Saving is disabled. Data cannot be entered or modified, and no queries, reasons, or missing codes can be added to any fields. Existing queries, reasons, and missing codes can be viewed, as well as any attached documents.

Leaving a CRF, by navigating to another CRF, visit, subject binder or logging out of DFcollect, unlocks the CRF.

1.8. Session Timeout

To maintain security, the DFcollect login session is automatically closed if there is no activity for the amount of time defined in DFcollect Preferences (see [Preferences](#) for details). The default session timeout is 10 minutes. Keep the session active to avoid being logged out.

Note

On some devices, the session timer may not be 100% accurate. The interval may be longer than indicated on slower CPUs or older devices.


























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























- an information dialog is presented to notify that the session has timed out
- 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 on the session timeout to terminate a session. Always save changes to the current CRF and logout.

1.9. Icon Reference Chart

This section lists all icons used in DFcollect along with their meanings.

-  - Application menu icon, on the login page.
-  - Application menu icon, after logging in.
-  - Back icon. Click to return to the previous page.
-  - Study not available icon, on the Studies page. The current study is not available.
-  - Add subject icon on the Subjects page. Click to add a new subject not listed on the page.
-  - Search icon, on the Sites and Subjects pages. Click to display the search field and enter the site or subject ID to search for. Click again to display the first search result.
-  - Search down. Click to move to the next search result.
-  - Search up. Click to move to the previous search result.
-  - Return to top. Click to return to the top of the page.
-  - Final subject binder. All data required at this time have been submitted, and there are no outstanding queries or missing required values.
-  - Incomplete subject binder. There may be missing required values, illegal values, or unresolved queries for this subject.
-  - Pending subject binder. There may be at least one document attached to the subject ID or pending data submitted for this subject.
-  - Blank subject binder. There is no data for this subject, or subject data has not yet been saved.
-  - 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.
-  - The CRF save button when the CRF has not changed and the app is online.


-  - The CRF save button when the CRF has not changed and the app is offline.
-  - The CRF save button when the CRF has changed and is not yet saved, and the app is online. Click to save changes to the database.
-  - The CRF save button when the CRF has changed and is not yet saved, and the app is offline. Click to save changes to local storage.
-  - The CRF save button when CRF changes have been saved successfully to the study database, while online.
-  - The CRF save button when CRF changes have been saved successfully to local storage, while offline. The changes must still be uploaded to the study database once back online.
-  - The CRF save button when the CRF is read only due to being locked by another user.
-  - The CRF save button when the CRF is read only based on user permissions.
-  - CRF conflict. Click to open the list of conflicts between data in local storage and data on the server.
-  - Field help icon on the data entry form. Click to display the field help information.
-  - Date picker icon on the data entry form. Click to open the calendar and select a date for the current field.
-  - Required icon on the data entry form, indicating that the current field must be completed.
-  - Query icon. Click to open the Query dialog for the current field. The icon will change color based on query status: blue (outstanding), orange (pending), or green (resolved). In addition, a small grey circle will indicate the number of queries on that field, if one or more queries have been added.
-  - Reason icon. Click to open the Reason dialog for the current field. The icon will change color based on reason status: orange (pending), blue (rejected), or green (resolved).
-  - Missing value icon. Click to open the Missing Value dialog for the current field. The icon will change to green in color if a missing value code has been selected.
-  - Reply to the query, in the multiple queries dialog (if enabled).
-  - Edit the query, in the multiple queries dialog (if enabled).
-  - Delete the query, in the multiple queries dialog (if enabled).
-  - Add a new query, in the multiple queries dialog (if enabled).
-  - Manage Documents, on the data entry form. The number of attached documents is shown in the red circle. Click to open the Manage Documents dialog.
-  - Add document, in the Manage Documents dialog. Click to select a document to attach.
-  - CRF help, on the data entry form. Click to open the CRF help dialog.
-  - Download data to local storage, in the Storage & Syncing dialog. After selecting sites and/or subjects to delete, click to download the data to local storage.

-  - Submit data to server, in the Storage & Syncing dialog. After selecting site and/or subjects to upload, click to submit the data to the server while online.
-  - Delete data from local storage, in the Storage & Syncing dialog. After selecting sites and/or subjects to delete, click to remove the data saved to local storage.
-  - Subject data has been downloaded to local storage. After download is complete, the date and time of download will appear below the icon.
-  - The downloaded subject data includes attachments.
-  - Subject data has been downloaded to local storage, in the Studies and Subjects page.
-  - Subject data has been downloaded to local storage, in the Sites page. The number inside the grey circle represents the number of subjects with data downloaded to local storage.
-  - Subject data has not been downloaded to local storage, in the Subjects page. Click to select that subject to download if online.
-  - The subject has been selected for download on the Subjects page but has not been downloaded yet.
-  - New subject data entered while offline is saved to local storage and not yet submitted to the server.
-  - Subject data changes entered while offline are saved to local storage and not yet submitted to the server.
-  - Data conflict, indicating that at least one data record has a conflict that must be resolved before submitting data to the server.


Chapter 2. Data Entry

2.1. Selecting a Subject

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

If the subject ID you need is not in the list, click  to add a new subject ID. 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 to confirm the subject creation, or to close the dialog without creating a subject.

2.2. Navigating the Subject Binder

The subject binder page displays the available visits for that subject. Under each visit, the CRFs available at that visit are presented. Click a visit to see the list of CRFs in that visit. To begin data entry, select the appropriate visit and CRF. To change to a different visit or CRF, click  in the CRF page header area to return to the subject binder page.

2.3. Entering Data / Completing a Record

2.3.1. Data Entry Aids

2.3.1.1. Focus Indicators

The last in-focused field displays a vertical bar on the left edge of the field. It may contain color information, including red (required and missing or illegal values), blue (outstanding query), green (resolved), orange (pending), and black (otherwise).



2.3.1.2. 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.

2.3.1.3. Legal Ranges

Some fields may have legal ranges defined. If you enter an illegal value, the value turns red, and you are shown a warning similar to: "Input value is not in the legal range." The warning disappears after a few seconds, though the value remains red until corrected.

2.3.1.4. Help

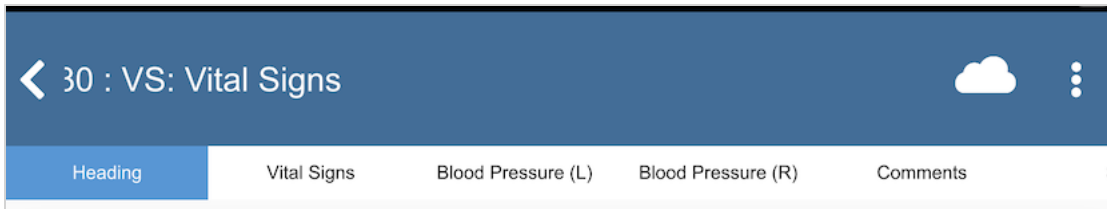
In addition to the description for each field on the CRF, help information may be available for the field. This is indicated with a  icon. Click  to view the help message.

2.3.1.5. Field Skipping

Keyboard navigation on DFcollect is not standardized on tablet devices, hence field skipping is not implemented. Navigate directly to fields by selecting them.

2.3.1.6. Screens

Some CRFs may be organized into multiple screens. A screen has a main body for data as well as a clickable tab to control visibility. Click a tab to switch to that screen.



If screens are not used on the CRF, the tab bar is hidden.

2.3.2. Data Types

2.3.2.1. Number

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

2.3.2.2. String

Except for the | character, 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.

2.3.2.3. Date

Use the date picker to select a date. 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.

2.3.2.4. Time

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

2.3.2.5. Choice

Only one response option can be selected for each choice field. The field is displayed as radio buttons if there are three or fewer response options, otherwise they are displayed in a drop-down menu. To clear a response on a radio button, click the currently selected radio button again. Drop-down menus show the empty response as the first option - use that to clear the response.

2.3.2.6. Check

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

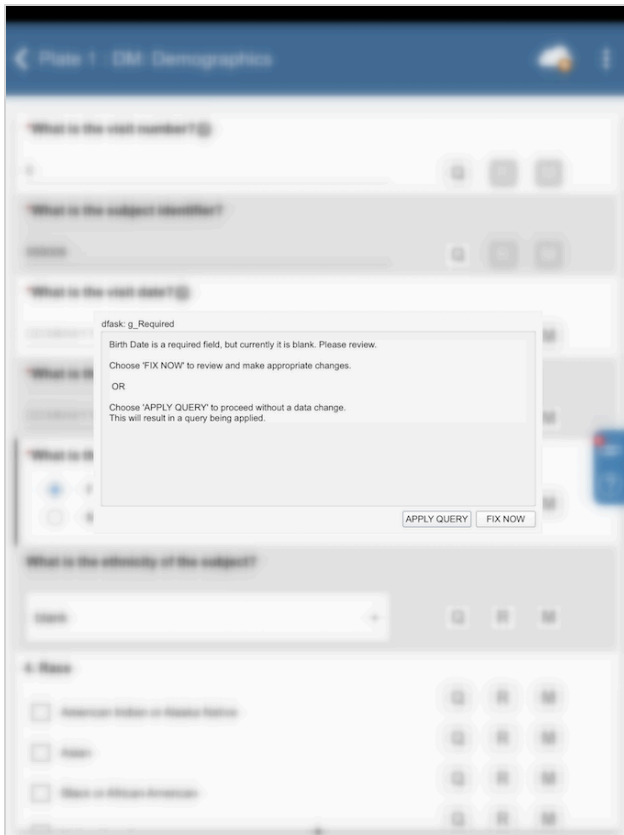
2.3.2.7. Visual Analog Scale (VAS)

Select a point along the scale by clicking that point. Drag the slider to select values more precisely. The selected value is shown above the scale in the middle, with the low and high limits of the scale shown on the left and right respectively. To remove the value, click **M**, select **No Code (Reset)** from the dropdown, and click **Apply**.

2.3.3. Edit Checks

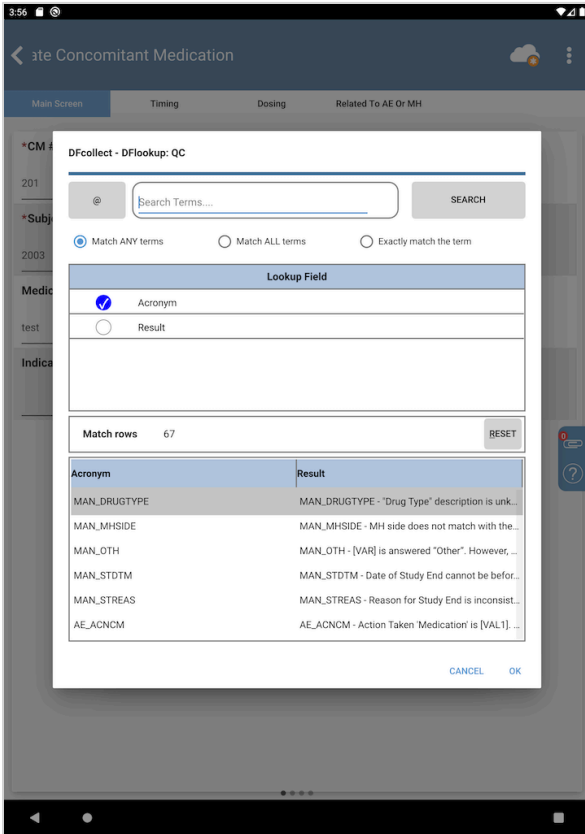
Edit checks are defined during study setup. They are fragments of logic that enforce study expectations for the data collected. They run interactively during data entry and data review. Edit checks may be run when you enter a CRF or a field, or when you leave a CRF or a field. Edit checks perform various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

The following is an example edit check. Your own study will likely have similar edit checks that also display messages and request input. In the edit check example shown below, the edit check has detected an inconsistency in the response. The user is asked to click **FIX NOW** to return to the data field to make a correction, or click **APPLY QUERY** to add a query to the field and fix the problem later.





2.3.3.1. Lookup Table Dialog

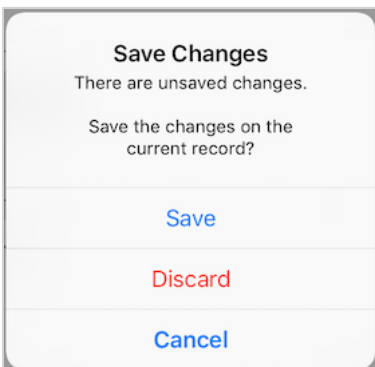
Certain edit checks may offer the opportunity to select a value from a lookup table. The behavior of lookup tables is identical to the behavior in **DFexplore**. For further information, refer to [DFexplore User Guide, Using Lookup Tables](#).



2.3.4. Saving Data



When you have completed data entry on a CRF, you must save your changes before leaving the CRF. To do so, click  if you are online, or  if you are offline, which are located in the Header Panel. If you are offline, you must remember to upload the changes to the server when you connect to a network. More details on this process, including handling conflicts, can be found in [Working Offline](#).

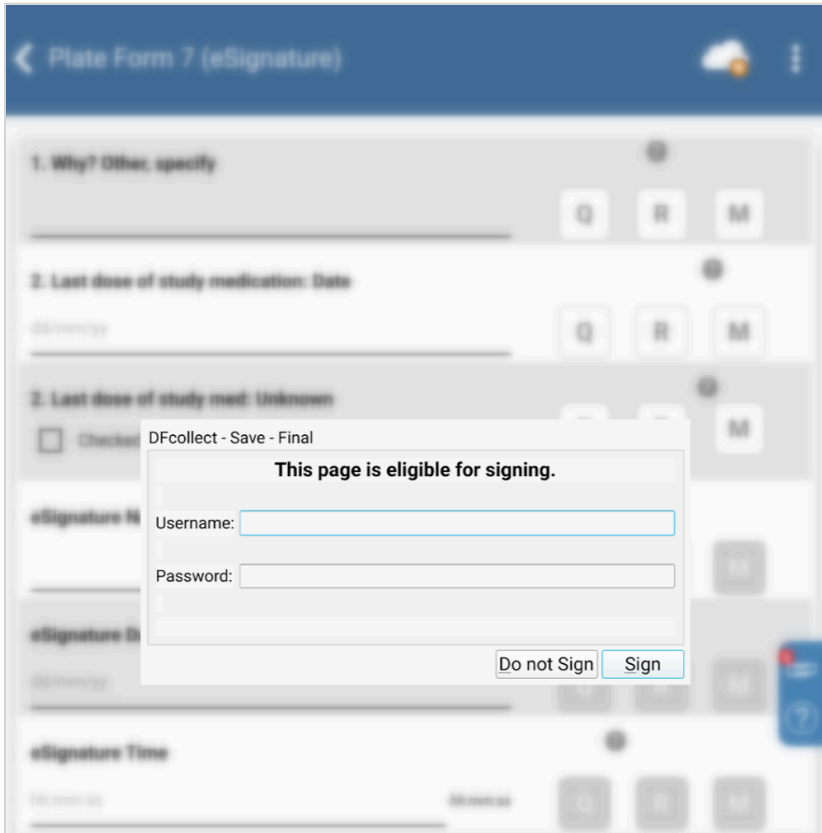
If you leave the CRF before saving, the following dialog is presented:



Click **Cancel** to remain on the CRF. Click **Save** to save your changes before leaving, or click **Discard** to discard the data on the CRF. If you discard the data, your changes are not saved and cannot be retrieved.

2.3.5. Electronic Signature

If the CRF you have saved requires an electronic signature, after clicking  if you are online, or  if you are offline, a dialog will appear indicating that the page is eligible for signing.



The screenshot shows a mobile application interface for 'Plate Form 7 (eSignature)'. The background is a CRF form with several sections: '1. Why? Other, specify', '2. Last dose of study medication: Date', and '2. Last dose of study med: Unknown'. A modal dialog box is centered on the screen, titled 'DFcollect - Save - Final'. The dialog contains the text 'This page is eligible for signing.' followed by two input fields: 'Username:' and 'Password:'. At the bottom of the dialog are two buttons: 'Do not Sign' and 'Sign'.

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 DFcollect.

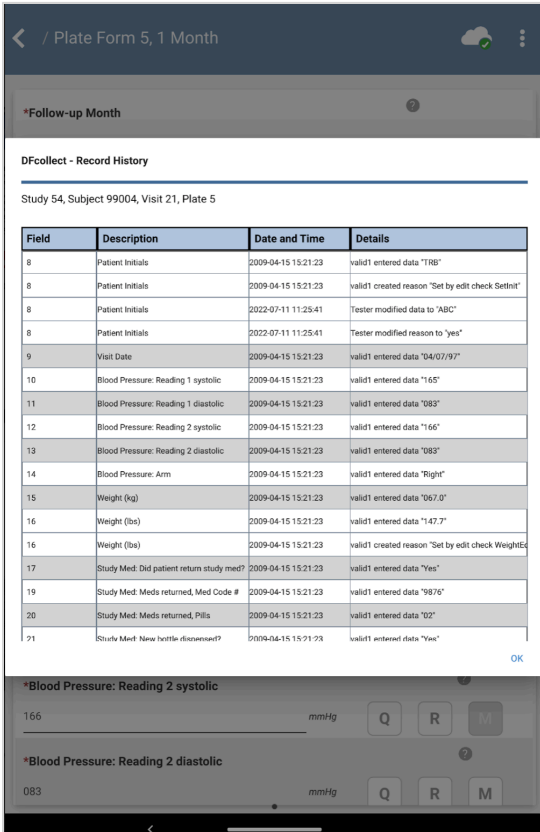
If you do not want to sign the record, click **Do not Sign** to save the CRF without providing your signature.

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.

2.4. Viewing Page History

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



The Page History dialog displays a table with the headers: field number, field description, date and time, and details. The details includes what changes were made to data and metadata along with the username of the person making the changes. All changes to a field are grouped together, from oldest change to newest change, with the background row color alternating for each field.

On smaller screens, the field number is not displayed, and you may need to scroll across to view the full details.

Click **OK** to close the dialog and return to the data entry screen.

Page History is only available while online. While offline, the Page History dialog will indicate that history of changes is not available.

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

2.5. Finding Subject Records

To return to the Subjects list from a subject binder or CRF, click **<** until you arrive at the Subjects list.

To search for a specific subject ID, click **🔍** to open the search bar. Type the subject ID into the search bar and click **🔍**. You are taken to the first subject ID in the list that matches your search. Click **⬇** and **⬆** to move to the next or the previous subject IDs that match your search. Clicking **🏠** takes you back to the first subject ID in the list that matches the search.

Chapter 3. Metadata

3.1. 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](#).

3.1.1. 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.

3.1.2. Edit Query

To edit a query, click **Q**. If the query is resolved, the Edit Query dialog opens. 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.

3.1.3. 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**.

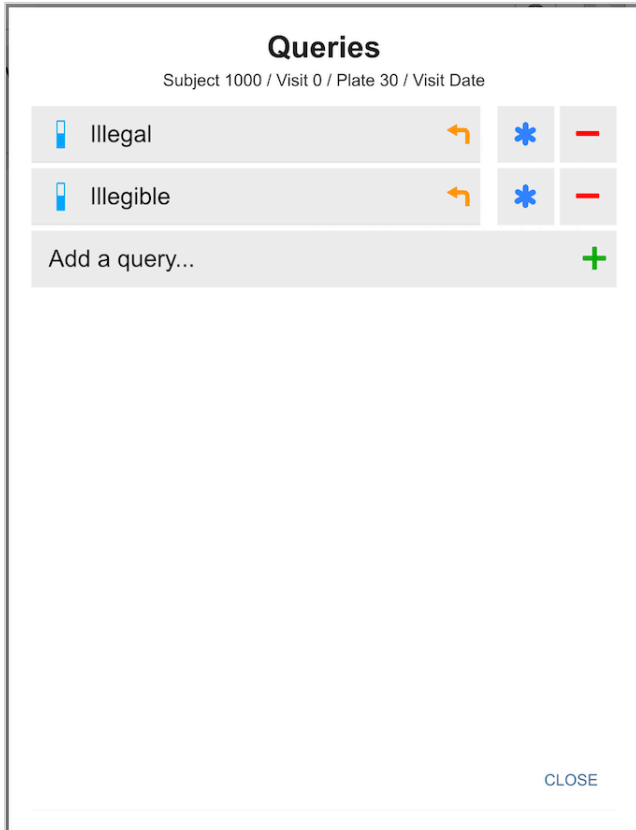
3.1.4. Delete Query

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 confirm deletion of the query on the field. At each step please ensure that the query really should be deleted.

3.1.5. Multiple Queries Dialog

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



The icons used in the multiple queries dialog are:

- ↩ Reply
- * Edit
- - Delete
- + Add

In single query per field studies there are navigation buttons at the bottom of each dialog to navigate from one dialog to another. These are not present in studies that permit multiple queries per field. 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.

3.2. 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 the 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.

3.3. 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 code 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 code 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 previously been marked as missing, click **M**. 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.

3.4. Resolving Queries

Queries can also be resolved via **Q**.

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


3.5. Managing Documents

DFcollect allows users to attach documents to any record, accommodating the collection and storage of data and information in other formats. This can be useful for managing images, or other recordings, that are relevant to the data of the current record.

3.5.1. Supported Document Types

DFcollect is able to upload, view and download PDFs, images, audio, and video. Specifically for images, DFcollect supports JPEG (JPG), PNG, and BMP formats; for audio, DFcollect supports MP3, and WAV formats; for video, DFcollect supports MP4, and AVI formats. The file size limit is 25 MB.

3.5.2. Reviewing Documents

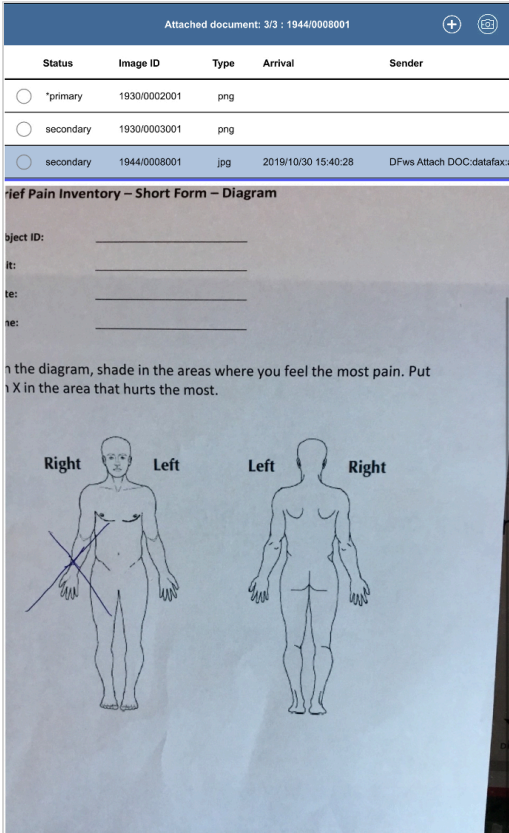
Click  in the CRF Menu to open the **Manage Documents** view. The number with the red background  is the current number of documents for this record.

The view includes a list of the available documents and a preview area. Each document in the list has several attributes:

- **Selected for download.** Checked (circle with yellow checkmark) or unchecked (empty circle).
- **Status.** One of "primary" or "secondary" and will generally be "secondary" indicating that this document is related to the data but not the primary source of the data.
- **Image ID.** A unique identifier for this document.
- **Type.** What is the document type? This is a file "extension" or acronym from a list of supported types.

- **Arrival.** The arrival time of the document to the study - when was it originally received or added.
- **Sender.** The "sender" of the document. This may include an email address, a username and identifier for another application, etc.

If there is at least one document, the first document is opened in the preview area. To view another document, select it from the list by clicking it. Documents may not be edited.



Many document types can be previewed directly, including PDF, JPEG (JPG), PNG, and MP4 format. Other formats can be downloaded to the local computer and viewed using appropriate 'helper' software.

3.5.3. Adding Documents

To add a document:

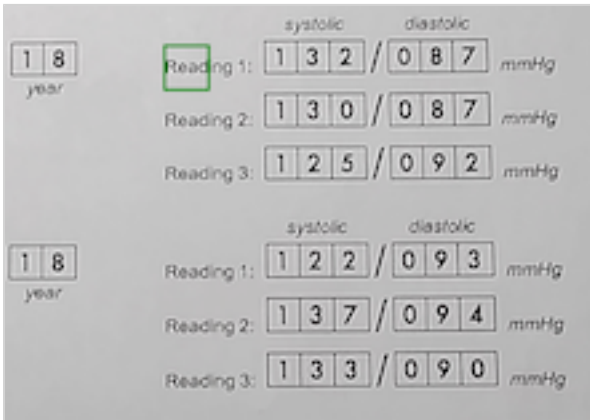
1. Add it using the device operating system's file browser. In the dialog header, click to open the file browser and select one file. The **Attach File** confirmation dialog appears. Click **Save** to confirm and add the file, or **Discard** to cancel the action.




Note

For iOS® users, if Optimize Storage is enabled on the device, iCloud Photos automatically manages the size of the photo library on the device. Original photos and videos are stored in iCloud and space-saving versions are kept on the device. Turn on the **Download and keep originals** setting on the iOS® device to have the *original* photos and videos available for upload to DFcollect.

2. Use the camera (if available) to take a photograph of the document. If the document contains multiple pages, each page must be photographed separately and becomes its own document. In the dialog header, click to open the camera

view. In camera view, the rear-facing camera is used as the default device to take photographs. For iOS devices, the camera view automatically adjusts focus. For Android devices, it is possible to manually focus the document view by tapping an area of the device screen. The tapped area is highlighted with a green rectangle. If the camera is unable to focus the tapped area, tap another area. Repeat if necessary until focus is acquired.




Click  in the bottom of the camera view to take the photo. After taking the photo, the camera view switches to the preview page. It is possible to retake the picture by clicking  again. The photo is added as a document by clicking .

Note




In Android™, to cancel submitting a photo from the preview page, you must use Android™'s back key to close the photo preview page.

3.5.4. Downloading Documents

Documents can be downloaded from [Manage Documents](#) view to local storage on the device. Click the empty circle in the left-hand column to select a document to be downloaded. Select additional documents as needed.

Click  to start downloading.

Example 3.1. One document selected for downloading

| Attached document: 13/28 : 1838/002D001   | | | | | |
|---|-----------|--------------|------|---------------------|---------------------------|
|  | Status | Image ID | Type | Arrival | Sender |
| <input type="radio"/> | secondary | 1838/002C001 | pdf | 2018/09/18 10:37:41 | DFws Attach DOC:datafax:5 |
| <input checked="" type="radio"/> | secondary | 1838/002D001 | pdf | 2018/09/18 10:37:49 | DFws Attach DOC:datafax:5 |
| <input type="radio"/> | *primary | 1842/0007001 | dcm | 2018/10/16 10:46:02 | DFws Attach DOC:datafax:t |
| <input type="radio"/> | secondary | 1842/0008001 | dcm | 2018/10/16 13:03:50 | DFws Attach DOC:datafax:C |

Note

The location of downloaded documents is different on iOS® and Android™. On iOS®, open the **Files** app and locate the named folder **dfcollect**. All downloaded documents are in this folder. On Android™, open the **Files** app and switch to **Downloads**. The downloaded documents are in the **DFcollect** folder.


Chapter 4. Tasks

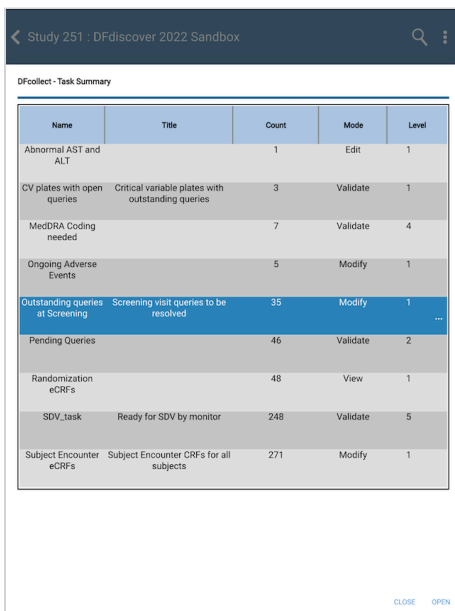
4.1. Task Listing

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


Note

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

To view your tasks, go to the Sites page and click  to open the Application Menu, and select **Task Listing** from the dropdown menu. The list of defined data tasks available to you will appear.




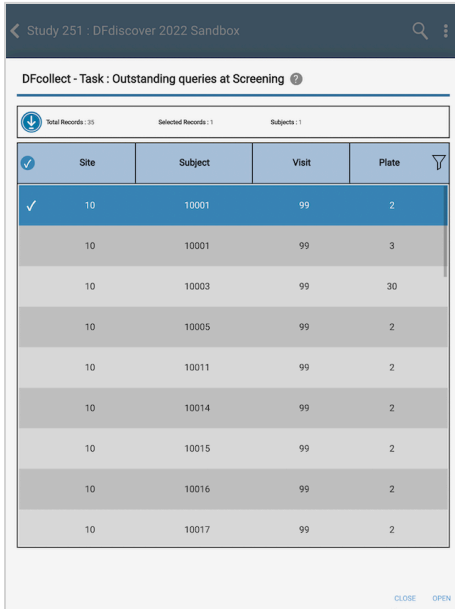
| Name | Title | Count | Mode | Level |
|----------------------------------|---|-------|----------|-------|
| Abnormal AST and ALT | | 1 | Edit | 1 |
| CV plates with open queries | Critical variable plates with outstanding queries | 3 | Validate | 1 |
| MedDRA Coding needed | | 7 | Validate | 4 |
| Ongoing Adverse Events | | 5 | Modify | 1 |
| Outstanding queries at Screening | Screening visit queries to be resolved | 35 | Modify | 1 |
| Pending Queries | | 46 | Validate | 2 |
| Randomization eCRFs | | 48 | View | 1 |
| SDV_task | Ready for SDV by monitor | 248 | Validate | 5 |
| Subject Encounter eCRFs | Subject Encounter CRFs for all subjects | 271 | Modify | 1 |

The Task Listing page includes the following information for each task: Name, Title, Count, Mode, and Level. The Name and Title provide information about the purpose of the task. The Count indicates the number of records that are included in this task. The Level and Mode provides technical details about what happens when you review and save the records in this task. You may need to scroll up and down to see all tasks in the table or scroll right and left to see all columns for each task. Click  at the end of the row to see more information about the task listing, including any instructions provided about completing the task.

Select any task on the Task Listing page and click **Open** to go to the Task page. To close the Task Listing page and return to the Sites page, click **Close**.

4.2. Task Results


After selecting a task from the Task Listing page, you will see the list of records available in that task. The task name is shown at the top of the page. Click  next to the task name for more details about the task.






| Site | Subject | Visit | Plate |
|------|---------|-------|-------|
| ✓ 10 | 10001 | 99 | 2 |
| 10 | 10001 | 99 | 3 |
| 10 | 10003 | 99 | 30 |
| 10 | 10005 | 99 | 2 |
| 10 | 10011 | 99 | 2 |
| 10 | 10014 | 99 | 2 |
| 10 | 10015 | 99 | 2 |
| 10 | 10016 | 99 | 2 |
| 10 | 10017 | 99 | 2 |



The Task page includes the following information for each task record: Site, Subject, Visit, and Plate. **Total Records** at the top of the table indicates the total number of CRFs in your task. To begin reviewing your task, select any record on the Task Results page and click **Open** to open the CRF.

While reviewing a CRF in a task, the CRF menu will indicate that you are reviewing this record as part of a task. Click **Task** in the CRF Menu to view details about the current task. Review and save the CRF as needed, following instructions provided, as you would during data entry.

Click  to return to the Task page and select another CRF to review or close the task. The Task page will refresh when you return to it, so that if the record you just saved no longer meets the task criteria, it no longer appears in the table.

The Task page also includes options to filter task records in the table and to download subject records for offline use.

To filter task records, click  to display search fields for each of the columns in the table. Enter a value in one or more search fields and click  to filter the records in the table. A message will appear at the top of the screen indicating the number of records found by the filter criteria. Click  to hide the search fields and remove the filter, displaying all records in the task again.

To download subject records for offline use, click one or more records in the table to select the subject(s) whose data you wish to download, or click the circle to the left of the Site column header to select all subjects in the task for download. Click the row again to unselect it if needed. **Selected Subjects** at the top of the table indicates the number of subjects to be downloaded. Click  to start downloading all records for the selected subjects. Once records are downloaded, the icon  will appear at the beginning of the row.

To close the task and return to the Sites page, click **Close**.


Chapter 5. Query View

5.1. Opening Query View

Query 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 **DFcollect** is connected to DFdiscover server and API version 5.5 or later.

To view data queries, from the Sites or Subjects page, click  to open the Application Menu, and select **Query View** from the dropdown menu.

DFcollect - Query Summary

| Site | Total Query | Outstanding | Pending | Resolved |
|------------------|-------------|-------------|-----------|-----------|
| 0 Seattle | 0 | 0 | 0 | 0 |
| 10 New York | 266 | 178 | 37 | 51 |
| 20 Austin | 39 | 26 | 8 | 5 |
| 30 Denver | 40 | 31 | 4 | 5 |
| 40 Atlanta | 40 | 39 | 0 | 1 |
| 50 San Francisco | 10 | 9 | 1 | 0 |
| 60 Cotonou | 112 | 106 | 1 | 5 |
| Total | 507 | 389 | 51 | 67 |

When you open Query View from the Sites page, the Query Summary appears, showing the number of total queries at each site you have access to as well the number of outstanding, pending, and resolved queries. The totals for all sites are shown in the last row. Select a site row in the table to highlight it, then click **Open** to see the list of queries for that site.

| Subject | Visit | Record | Field | Category | Status |
|---------|-------|--------|--|---------------|-------------|
| 10003 | 10 | 225 | Platelets Result | Illegal | Outstanding |
| 10003 | 99 | 30 | Height Not Done | Other | Outstanding |
| 10005 | 0 | 26 | 4. Is the subject a re-screen | Other | Outstanding |
| 10005 | 0 | 225 | Result (WBC) | Illegal | Outstanding |
| 10005 | 10 | 10 | If no, provide reason | Missing | Outstanding |
| 10005 | 10 | 463 | 1. Which Visit did the participant miss? | Missing | Outstanding |
| 10005 | 99 | 2 | Visit Date | Other | Outstanding |
| 10005 | 99 | 2 | Mark or sign study screening consent | Other | Outstanding |
| 10005 | 30001 | 300 | MH Page (1) CM | Missing | Outstanding |
| 10006 | 0 | 30 | 2. Weight | Inconsistent | Outstanding |
| 10011 | 0 | 1 | Missing Page | Overdue Visit | Outstanding |

When you open Query View from the Subjects page, the Queries page displays all outstanding queries for this site and includes the following information for each query: Subject, Visit, Plate, Field, Category, and Status. At the top of the table, **Subjects** shows the number of subjects currently selected and **Total Rows** indicates the number of queries that appear in the table.

To see more detail about any query in the table, click the row to select it, then click **...** to open a dialog showing full details about the query. Click anywhere outside the dialog to close it.

The Queries page also includes options to filter queries by status, category, and timing, to download data records with queries for offline use, and to view reports about queries at this site.

To filter the queries that appear in the table, click **▽** to display the filter options for query modification timing, category, and status. Use the dropdown menu to select the desired options, and the table will update immediately. Click **✕** to reset the filter options. Click **☑** to hide the filter options.

To download queries for offline use, click one or more rows in the table to select them, or click the circle to the left of the Subject column header to select all records in the table. Click the row again to unselect it if needed. The **Subjects** number at the top of the table will update as rows are selected. Click **⬇** to start downloading all data for the selected subjects. Once a subject's data is downloaded to your device, the icon **⬇** will appear at the beginning of the row.

To view reports about queries at this site, click **?** next to the site name at the top of the screen. The reports include:

- **Query Status in Site.** Pie chart of queries by status at this site, including outstanding (blue), pending (orange), resolved (green).
- **Query Category in Site.** Pie chart of queries by category at this site, including categories missing, illegal, inconsistent, overdue visit, missing page, and others.
- **Query Distribution in Site.** Bar chart showing number of subjects, visits, records, and fields with total, outstanding, pending, and resolved queries.
- **Queries in Site Subjects.** Bar chart showing the total number of subjects at this site alongside the number of subjects with any queries, with pending queries, with outstanding queries, and with resolved queries.

- **Queries per Subject.** Table showing number of pending, outstanding, resolved, and total queries per subject. Click any subject row to highlight it, then double-click to close the report dialog and filter the list of queries to show only the selected subject.

Swipe to view each report. Click outside the dialog to close it.

To close the Queries page and return to the Sites or Subjects page, click **Close**.

5.2. Reviewing Queries

To review a query, click a row in the Queries table to highlight it, then click **Open** to open the CRF and go to the field where the query is located. Click **Q** to open the query dialog.

The CRF menu will indicate that you are reviewing queries, with a small pie chart showing the status of queries on that CRF page. Click **Query** in the CRF Menu to see how many outstanding queries remain on the current CRF page. Review and resolve the queries and save the CRF as appropriate, as you would during data entry.

Click **←** to return to the Queries page and select another query to review or close the Query View.


Chapter 6. Working Offline

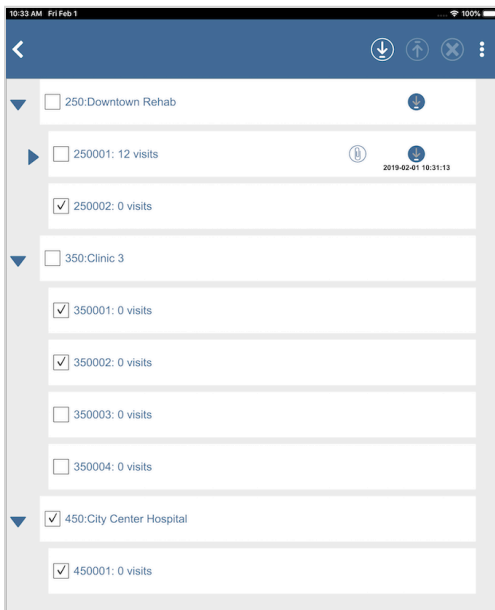
6.1. Prepare To Go Offline



If you are planning to view, enter, or modify data while not connected to the internet (offline), you must in advance, while connected to the internet, download the data to local storage on your device.


There are a few ways to download data to local storage. The first way is from the Storage & Syncing page, accessed via the application menu. You can also download data from the Subjects page, from Query View, and from the Task dialog.

6.1.1. Downloading from Storage & Syncing

Log in to DFcollect while online. Navigate to the study you intend to work with offline, click  to open the Application Menu, and select **Storage & Syncing** from the dropdown menu. This displays the list of sites and subjects you have access to and whether they have been downloaded to local storage.



You select the sites or subjects to download by clicking the checkbox in front of the site number or subject ID. Click  to expand a site or a subject. You can also expand the subjects and visits if they have been downloaded to local storage. Click  to collapse the expanded items.

After identifying the site(s) and/or subject(s) to download, click  to start the download to local storage. A **Download Progress** dialog opens while the download is in progress and closes automatically when complete.




The data are now available to view and modify while offline.


Store only the data needed

While it can be tempting to include all of the permitted sites and subjects in local storage, this is not recommended. Depending upon the network speed, it can take a considerable amount of time to download the requested subjects

and attached documents. It will also require local storage in which to keep the downloaded content. Finally, when you are online again, a comparison must be done against each record in local storage to determine if it needs to be uploaded, and if yes, to upload it again.





It is far more efficient to download only the subjects or sites that you will require while working offline.

The icon  to the right of a site name indicates this site has downloaded data in local storage. The  icon to the right of the subject ID indicates that it has been downloaded, and includes the date and time it was downloaded. The  icon next to the subject ID indicates this subject also has documents downloaded.

The Studies, Sites, and Subjects pages also indicate which data has been downloaded to local storage. The icon to the right of the subject ID is updated to show . The same icon is displayed in the Studies page. In the Sites page the same icon is also displayed along with the number of subjects downloaded.




To refresh existing downloaded data, repeat the above steps to re-download.

6.1.2. Downloading from Subjects Page




Log in to DFcollect while online. Navigate to the study and site of interest. Click  to the right of the subject ID to select that subject for download. The download icon updates to  indicating that the subject is selected for download. You may select multiple subjects at a time. Then click  in the header to start downloading the selected subjects. The number in the header to the left of the header download button indicates the number of subjects chosen to download. Once downloaded, the icon to the right of each subject ID is updated to . The same icon is displayed in the Studies page. In the Sites page the same icon will also be displayed along with the number of subjects downloaded.

To refresh existing downloaded subject data, repeat the above steps to re-download.

6.1.3. Downloading from Query View


Log in to DFcollect while online. Navigate to the site of interest and click  to open the Application Menu, and select **Query View** from the dropdown menu. Click one or more rows in the table to select them, or click the circle to the left of the Subject column header to select all records in the table. Click the row again to unselect it if needed. The **Subjects** number at the top of the table will update as rows are selected. Click  to start downloading all data for the selected subjects. Once a subject's data is downloaded to your device, the icon  will appear at the beginning of the row.


6.1.4. Downloading from Task Dialog


Log in to DFcollect while online. Navigate to the Sites page and click  to open the Application Menu, and select **Task Listing** from the dropdown menu. Select any task on the Task Listing page and click **Open** to go to the Task page. Click one or more records in the table to select the subject(s) whose data you wish to download, or click the circle to the left of the Site column header to select all subjects in the task for download. Click the row again to unselect it if needed. **Selected Subjects** at the top of the table indicates the number of subjects to be downloaded. Click  to start downloading the all records for the selected subjects. Once records are downloaded, the icon  will appear at the beginning of the row.





6.2. Offline Data Entry

To use DFcollect offline, you can simply login while not connected to the internet, or you can set DFcollect to be offline even if you are connected to the internet (Wi-Fi or cellular).




To set DFcollect to be offline, on the login page, click  and select **Preferences**. Slide **Offline Only** to the right (on). After logging in, you will see a red line across the top of the page to indicate that you are offline.

If you leave **Offline Only** off and are not connected to the internet while in DFcollect, the Save button in the header of the CRF will display as  to indicate that you are offline.


After data have been downloaded to local storage, the process of data entry is the same while offline as it is while online, except for how data is saved. Instead of being saved to the server, the data is saved to local storage on your device, shown by  in the header of the CRF.


When a CRF is saved successfully offline, in the visits and plates page, there is an additional  icon next to a plate (when the visit is expanded) or next a visit (when the visit is collapsed). Likewise, the  icon also appears in the Subjects and Sites page. When data for a new subject is added while offline, in the Subjects page you will see  along with the  icon next to the newly created subject. Once you are back online, the data must be submitted to the server.

6.3. Submit Data to Server

To submit data to the server that was entered while offline, click  in the page header and select **Storage & Syncing**. In this view, you select the subjects or sites you want to upload (generally this would be all of them), then click  to submit data to server. An **Upload Progress** dialog appears while the upload is in progress and closes automatically when complete. The  icon will no longer appear next to that subject and site, confirming that the data has been saved on the server.

6.3.1. Conflict Resolution

A data conflict may occur if there were changes made to data on the server after data were downloaded to local storage, and then inconsistent changes are submitted back to the server from local storage. Conflicts must be resolved by either verifying that the server values are correct or submitting the local storage values to the server. Conflicts are indicated by a .

To resolve the conflict, open the CRF with the conflict and click  in the header of the CRF to display the Conflict details. Review the conflicts listed and click **Select server value** or **Select local value** to indicate which data to keep, and then click **Submit** to submit the data to the server.



Conflict Table (total 6 conflicts)

| Field | Server value | Local value |
|---------------------------------------|---------------------------|----------------------------------|
| What is the visit date? | 11/DEC/2018 | 12/DEC/2018 |
| What is the subject's date of birth? | 11/DEC/1980 | 12/DEC/1980 |
| What is the ethnicity of the subject? | NOT HISPANIC OR LATINO | HISPANIC OR LATINO |
| 4. Race | Unchecked | American Indian or Alaska Native |
| 4. Race | Black or African American | Unchecked |
| 4. Race | White | Unchecked |

If the local value is selected, the fields with changed data will have a pending reason attached automatically to indicate the data change. The reason detail shows both server and local data value. If the server value is selected, the data on the server will not change and no reasons will be added.

6.3.2. Delete Data from Local Storage

Data in local storage is not automatically deleted after it is submitted. Instead it must be explicitly deleted. Before deleting, ensure that all local changes have been successfully submitted to the server.

To delete data from local storage, click  in the page header and select **Storage & Syncing**. Select the site(s) and/or subject(s) to delete, click , and click **Apply** when prompted. The data will no longer be available offline.

If subject data has been added or modified while offline and not yet submitted to the server, it must be submitted before you delete it from local storage. If you forget to do this and try to delete the data in local storage, you are notified that you are deleting records from storage that have not been submitted to the study server.

Submit all offline data before deleting

If you click `Ignore`, you are choosing to ignore the warning and the data saved to local storage will be lost. This might be useful if you are testing, or performing training, and the test data should not be saved centrally. But this is an uncommon situation.

In general, you must ensure that all locally stored data is submitted before it is deleted.

Click `Cancel` to cancel deleting the data from local storage.

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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.1.13. QtAV

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A.1.15. c3.js

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A.1.16. d3.js

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