

DFExplore User Guide

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Preface

DFdiscover Release 5.11.0

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Getting Help

For software support, Please contact the DFdiscover team:

- via email, help@dfnetresearch.com.
- Visit our website, <https://www.dfnetresearch.com>.

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.c.
- 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 **Button**.
- Menus and menu items are shown as: **File** > **Exit**.

Introduction

What is DFExplore?

DFExplore is a computer application used to enter, review and modify subject data, and to submit it over the internet to a **DFdiscover** server at the study coordinating site. This type of data entry is commonly referred to as Electronic Data Capture or EDC. **DFExplore** is part of the **DFdiscover** clinical trial management system, which also supports data collection by paper, scanned document and fax. All methods can be used in the same study. EDC has been described as having the advantage of providing immediate help to data collection users, resulting in more complete and accurate data entry, and fewer queries from the study coordinating site.

To help realize these benefits and facilitate the transition from paper forms to EDC, **DFExplore** has been designed with:

- intuitive navigation, using a subject binder analogy,
- data entry screens that can match the equivalent paper forms,
- help in the form of status icons, color coding, messages and interactive edit checks,
- a Query window used to read and respond to queries from the study coordinating site,
- a Reason window used to explain unusual data values (and thus avoid queries), and
- a Missing Value window used to mark fields with standard missing value codes

What type of computer do I need?

Versions of **DFExplore** are available for: **Windows 10 or later**, **macOS 10.14 (Mojave) or later**, and Linux. If you plan to use **DFExplore** on more than one computer you will need to install the appropriate version on each computer.

Your trial coordinating site may have more detailed instructions regarding computer needs.

What type of web browser do I need?

DFExplore is a standalone application. It does not rely on a specific web browser. It is downloaded and run on your local computer.

DFExplore can also be deployed through an application server hosted by the study sponsor. This deployment, known as **DFnavigator**, works in current versions of the Edge, Chrome, Firefox and Safari browsers, and possibly others.

Is data transmission over the internet secure?

DFExplore communicates with the **DFdiscover** server via encrypted communication on port 443. This port must be open on any firewalls between the local computer and the study server.

The security of the communication is based upon 3 industry standard technologies:

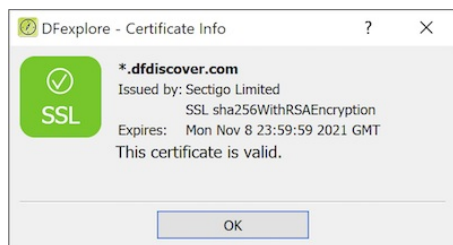
1. Communication protocols, namely TLS 1.2 or 1.3,
2. Strong encryption ciphers, and
3. Independent certification and confirmation of the server.

This is industry-standard technology that encrypts the bi-directional communication using a **certificate of trust** provided by the server. It is the same technology used by banks and the majority of secure, global web services.

You can visually confirm that the communication is secure by examining the details of the communication protocol and encryption cipher. Click the green lock icon next to the **DFdiscover Server** during login.



You can also examine the certificate of trust. After login, select [Help](#) > [Certificate Info](#) and look for the green checkmark.



What kind of response time can I expect?

As with all internet applications, response time and speed depends primarily on the speed of and traffic on your internet connection, and to a lesser extent on the distance between you and the study **DFdiscover** server (the distance itself is not the factor, but is generally impacted by the number of intermediate connections between the endpoints, and that can be a factor).

If you have a cable internet connection, you can expect login times in the range of 5 to 20 seconds and then 1 to 4 seconds to display each new page in the data entry window. Fibre connections are much quicker. Once a page is on the screen, moving between data fields is very fast, with essentially no delay.

NOTE: Your administrator may have enabled local caching of study setup information (but never data) for one or more studies that you have permission to access. This will shorten start times for repeated uses of the same study. There is nothing that you need to do to enjoy this benefit.

You can clear all locally cached study setup information by selecting **File** > **Clear Cache**. This is recommended, for example, when you stop working with a specific study.

How complicated is this going to be?

With a little practice, you should find that completing data collection pages in **DFExplore** is as easy as completing a printed version of the same page. In addition, the guidance provided by color coding (e.g. illegal values appear red) and the messages displayed by data consistency checks help you identify problems that can be corrected immediately or explained by entering a reason for unusual values. This advantage over paper forms helps you avoid queries and requests for corrections from the study coordinating site, thus saving you time in the long run.

Is any subject data stored on my local hard drive?

No; all subject data is sent to and retrieved from the **DFdiscover** server. As a result, you can access the study from any computer on which **DFExplore** has been installed. Different users can access their studies from shared computer(s), as each user is uniquely identified by a username and password combination.

Can anyone impersonate me within **DFExplore**?

Your username plus a password constitute your unique electronic signature. This may be your **DFdiscover** login credentials or your Microsoft login credentials, if supported for your **DFdiscover** server. By protecting your username and password, and making sure you logout of **DFExplore** before leaving a computer, you can ensure that no one can impersonate you and perform data entry that is attributed to you.

Permission to read, write and modify subject data is defined by the study coordinating site for each username. These permissions determine which study, sites, subjects, visits and individual data pages each user can create, view and modify. It would not be uncommon for more than one person to have permission to enter data for the same subject at a given clinical site; however, all data entry is recorded with your username, date and time. Thus a complete history is maintained of all database transactions.

What if I forget my password?

You can independently reset your password provided that:

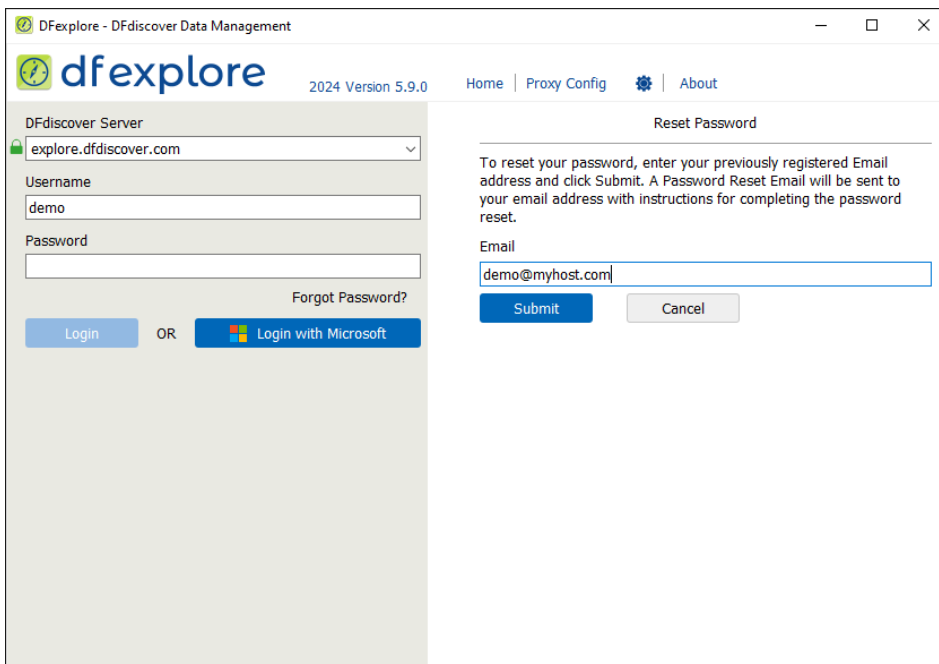
- you have a current email address registered on the server you are trying to access, and
- the sponsor has enabled resetting of passwords from the login dialog on that server.

If these conditions are satisfied, follow these steps in the login dialog to reset your password.

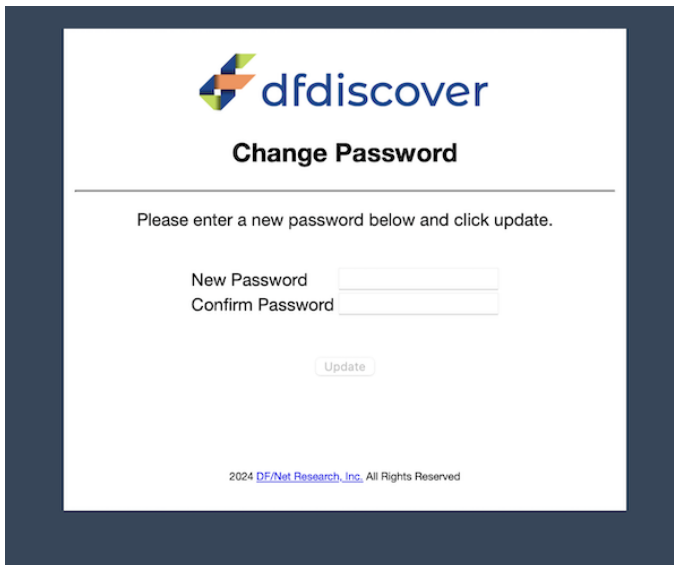
IMPORTANT: Please directly contact the sponsor's **DFdiscover** administrator for assistance in resetting your password, if

- you do not have a current email address registered on the sponsor's server, or
- the sponsor has not enabled resetting of passwords from the login dialog on that server.

1. Enter the value for **DFdiscover Server** and your **Username**.
2. Click **Forgot Password?**.



3. In the **Reset Password** panel, enter your email address; this must match the email address previously defined for you on this server.
4. Click **Submit**.
5. The confirmation message **Instructions to change password has been emailed to you** is displayed if the email address matches.
6. An email containing a link to reset your password is sent to the email address, with the subject line **DFdiscover Password Reset**. If you do not receive the email after waiting a few minutes, check your spam or junk folder.
7. Click the link in the email to open it in your browser. Follow the instructions to set a new password.



8. Return to **DFExplore** and enter your new password in the **Password** field and click **Login**.

Note that this process applies to your **DFdiscover** password only. If you are using Single Sign On with Microsoft to login to **DFExplore**, use the Microsoft forgot password option to reset your password before logging in to **DFExplore** using the **Login with Microsoft** option, if available for your server.

How hard is it to navigate among the various study forms for each subject?

A subject binder, complete with printed forms organized by study visits from beginning to end, with tabs identifying each visit, is quite easy to use.

DFExplore follows this subject binder analogy in Data View. When you open a clinical site (like walking into your office) you see a list of subject icons (like subject binders on a shelf). Double-clicking a subject icon opens the binder to reveal the list of visits that comprise all subject visits from beginning to end of the study.

Double-clicking a visit opens that section of the binder to show the data collection pages for that visit. When you are finished reviewing or entering data, double-clicking an open visit or subject binder closes it.

Each visit, and page within a visit, has a text label describing what it is, and colored icons that identify whether it is required or optional, blank or containing data, and, if data is present, whether it is complete or incomplete.

In addition to the Data View, there is a Queries View that lets you review data queries from the central office and jump to each relevant data field, where you can enter a reply, explain or correct the data value.

This familiar organization, along with the use of icons and color, makes navigating the study forms as easy as using a printed subject binder - perhaps even easier.

Can I use **DFexplore** for more than one study at a time?

Yes. The login screen asks you to specify the unique name of the **DFdiscover** server at the study coordinating site. Once you connect to the desired server you see a list of all studies you are permitted to access.

It is possible to participate in one or more studies with a single coordinating site and also possible to participate in studies at more than one coordinating site. In all cases the software behaves the same; only the study data entry forms differ.

If I don't like this, or don't have time for it, can I switch to another method of data collection/entry?

DFdiscover is capable of supporting EDC and paper data collection forms (scanned, emailed, faxed) within the same study, with no additional study setup work. Further, the design of the paper forms and data screens are identical and are completed in the same step; thus switching a clinical site from **DFexplore** to completing and scanning paper forms is certainly possible, and provides a fall-back position for sites that are unable to perform EDC. Of course, it is also possible to move in the other direction, switching from paper and scanning to EDC.

What are the technical requirements if I choose to submit paper CRFs?

There are many brands and manufacturers of scanning devices. It is not possible to recommend one specific model. However, almost all devices currently available are able to provide these minimum functions:

- Save scans to PDF, version 1.3 or higher. Scans of multiple pages can be saved to one document
- Offer 200 (or 300) dpi scan resolution. 200 dpi is more than sufficient resolution for documents containing primarily text
- If you are scanning, being able to email directly from the device saves time and creates a more efficient workflow. Having an email interface and network connection are important
- Greyscale scanning is preferred. Color may be useful but will generate scan documents that are very large and should be avoided unless absolutely necessary
- Each document scan has a maximum file size limit of 25 MB

How do I get started?

First you need to download and install **DFexplore** following the instructions provided by the study coordinating site.

After installation, on starting **DFexplore** and in the login dialog, enter the name of the **DFdiscover** server, your username, and your password; all of these values are provided by the study coordinating site. If supported by your **DFdiscover** server, you may log in with your Microsoft account that has been linked to your **DFdiscover** account. See [Login with Microsoft](#) for more details.

After successful login you are presented a list of the studies in which you are participating, each with a status indicating whether the study is currently available or off-line for maintenance. If a study is available, double-clicking the study entry connects to the study database.

After I connect to a study how do I enter subject data?

If you are not already in the Data View, select **[View] > [Data]**. The clinical sites for which you have permission are listed on the left side of the screen. Double-clicking a site opens it to reveal the list of subject binders. Double-clicking a subject binder opens it to reveal the study visit tabs, and double-clicking a tab opens the visit to reveal the data entry pages for that visit. You can then enter data, add reasons to explain unusual values, and reply to outstanding queries.

When you are finished with a page, to save your work in the study database at the coordinating site, click one of 3 save buttons at the bottom of the data entry window: **[Final]** (to indicate that data entry is complete), **[Incomplete]** (to indicate that some fields are incomplete or some queries remain to be answered), or **[Pending]** (to indicate that you have not yet finished your work with the page and want to finish it before it is reviewed by the study coordinating site).

What do I do when I'm finished entering subject data?

You can close a visit by double-clicking the open visit tab, and close a subject by double-clicking the subject icon. Only one subject binder can be open at a time; opening a new one automatically closes the open one (if any). When you are finished entering data for all subjects, logout by selecting **[File] > [Exit]**.

Your administrator may have enabled local caching of study setup information (but never data) for one or more studies that you have permission to access. This will shorten start times for repeated uses of the same study. There is nothing that you need to do to enjoy this benefit.

You can clear all locally cached study setup information by selecting **[File] > [Clear Cache]**. This is recommended, for example, when you stop working with a specific study.

Please directly contact the sponsor's DFdiscover administrator for assistance in resetting your password, if

- You do not have a current email address registered on the sponsor's server, or
- The sponsor has not enabled resetting of passwords from the login dialog on that server.

A Guided Tour

This chapter provides a brief introduction to **DFExplore**. It begins with a description of how to login to a **DFdiscover** study server, and then describes each of the major components in the application.

Login

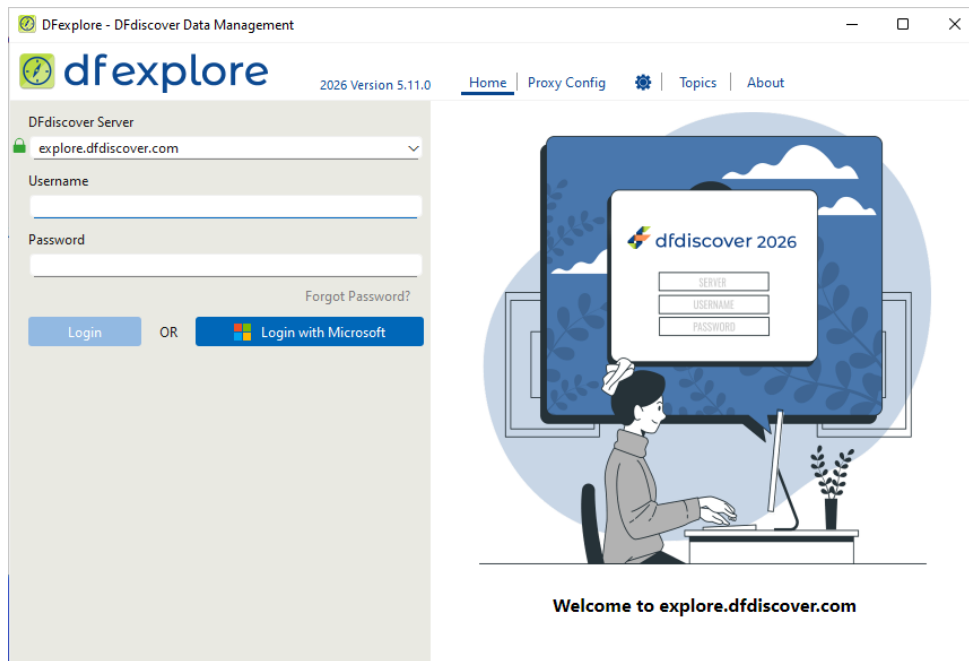
To work in a study database you must first start **DFExplore** and login to the **DFdiscover** server where the study data and configuration information are stored. This requires an internet connection. The study coordinating site will have provided you with:

- the **DFExplore** application **Windows 10, macOS 10.14 (Mojave) or later** and **Linux** versions are available,
- the name of the **DFdiscover** server,
- your username,
- your initial password, and
- the name of the study (or studies) for which you have permission to access on the **DFdiscover** server.

The login process involves authenticating to the **DFdiscover** server and then selecting the study with which to work.

Authenticating

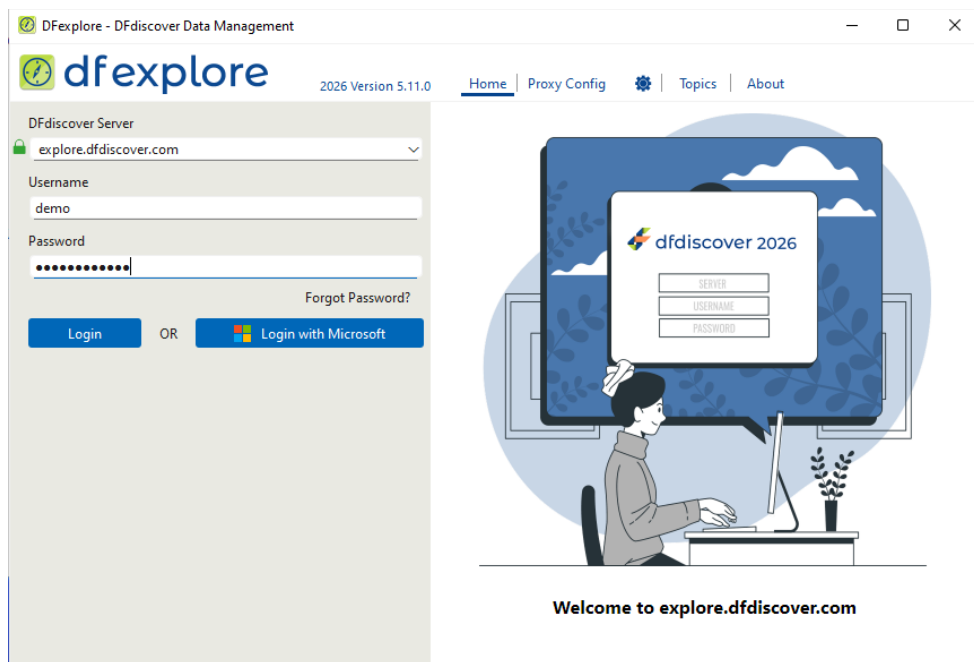
The initial login dialog has the following appearance. The left-side panel shows 3 input fields for **DFdiscover Server**, your **Username** and your **Password**. The right-side panel shows the software logo and version. The contents of this panel can also be customized by the system administrator. A ribbon of clickable options stretches across the top of both panels.



In the left-side panel, enter the value for the **DFdiscover Server**. If the system administrator has defined a customized login screen, the contents of the right-side panel refresh to show this screen. A green lock icon also appears next to the **DFdiscover Server** field. The icon is confirmation that a secure connection with the server has been established. Optionally, click the icon and review the details of the connection.



Enter your **Username** and **Password**.



Notice that your password is obscured as you type it. This is a standard security practice to ensure that anyone else looking at your screen cannot see the entered password. If **Caps Lock** is enabled on the keyboard, the message *Caps Lock is On* appears as a tooltip as the password is typed. It does not appear for any other field in the application.

If your IT department has installed a proxy server (to filter requests sent to other servers on the internet), click the proxy server configuration button ([Proxy Config](#)) to access the **Configure Proxy Server** dialog. You will need the specific configuration values from your IT department.

Click **Login**.

DFExplore remembers the most recent servers (and proxy servers) you have specified, so you will only need to enter this information once, but your username and password need to be entered each time you login.

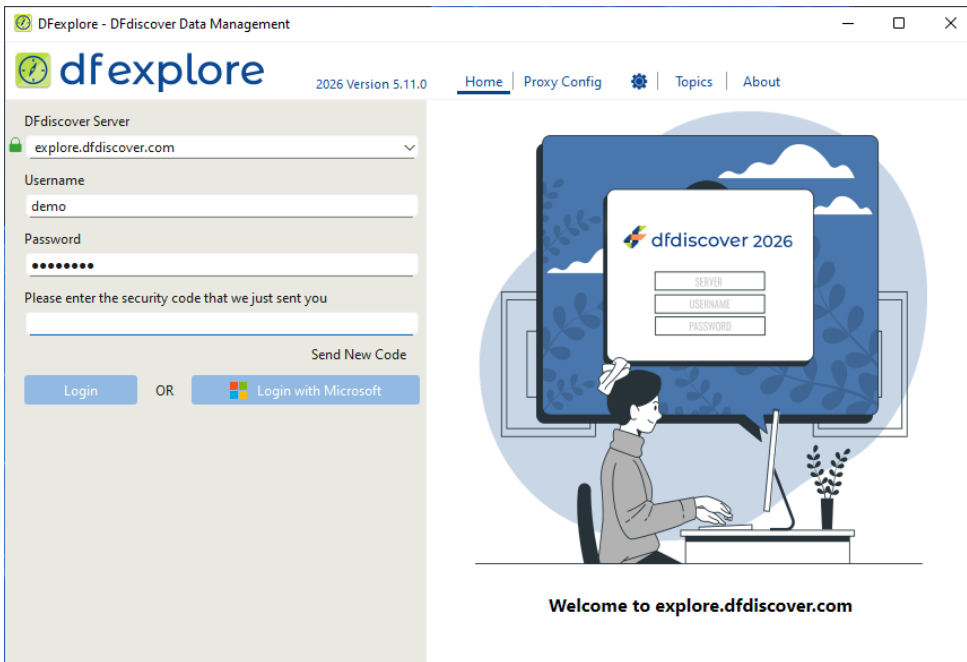
The first time you connect to a **DFdiscover** server, you are prompted to change your password. All data entered and modified is recorded under each user's username. Be vigilant to protect your username and password.

If you forget your password, you can request a password reset from the login dialog. First enter the server name and your username into the login dialog, then click **Forgot Password?**. You are asked for your email address, which must match the email address for you on this server. A link to reset your password is emailed to you. Click the link and follow the instructions to set a new password, then return to the login dialog to log in with your new password. This feature is only available if it has been allowed by the DFdiscover administrator.

DFExplore includes password aging, an FDA regulatory requirement. After the expiry period has elapsed, you are prompted to reset your password the next time you login.

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.



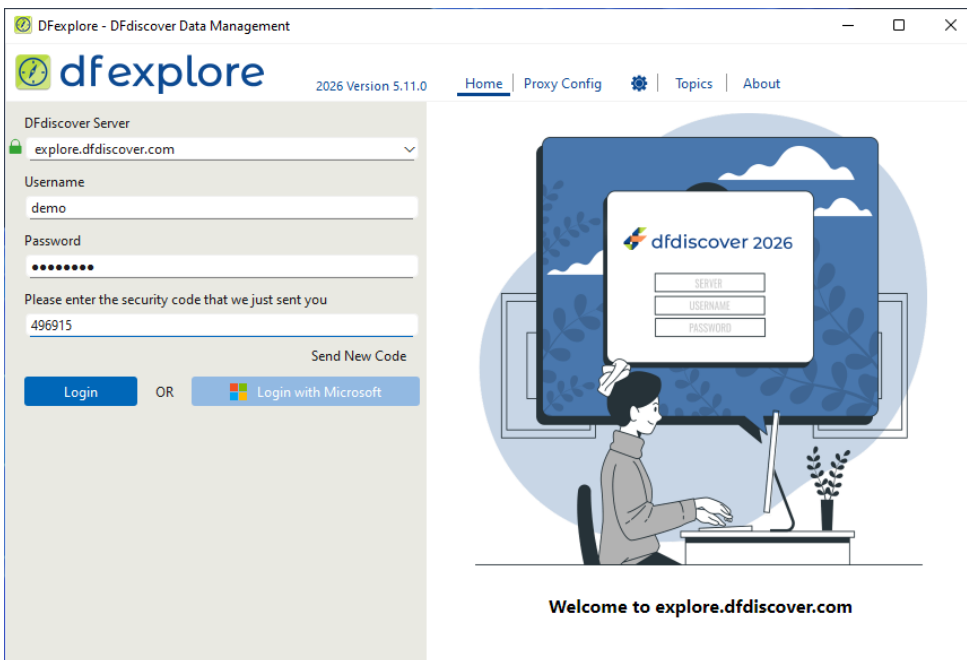
You will receive a 6-digit security code in an email or an SMS message, depending on which is configured for your account. The email is sent to the email address on file for the account. The SMS message is sent to the phone number on file for the account.

TIP: If you do not receive the email after waiting a few minutes, check your spam or junk folder.

datafax@explore.dfdiscovers.com
Security Code for explore.dfdiscovers.com
To:

995978
Use this code for DFdiscover verification.

Enter the 6-digit security code in the field labeled **Please enter the security code that we just sent you.**



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.

Each verification in two-factor authentication, with the same credentials, and device is valid for 30 days. Logging in with different credentials and/or a different device will again initiate two-factor authentication.

Login with Microsoft

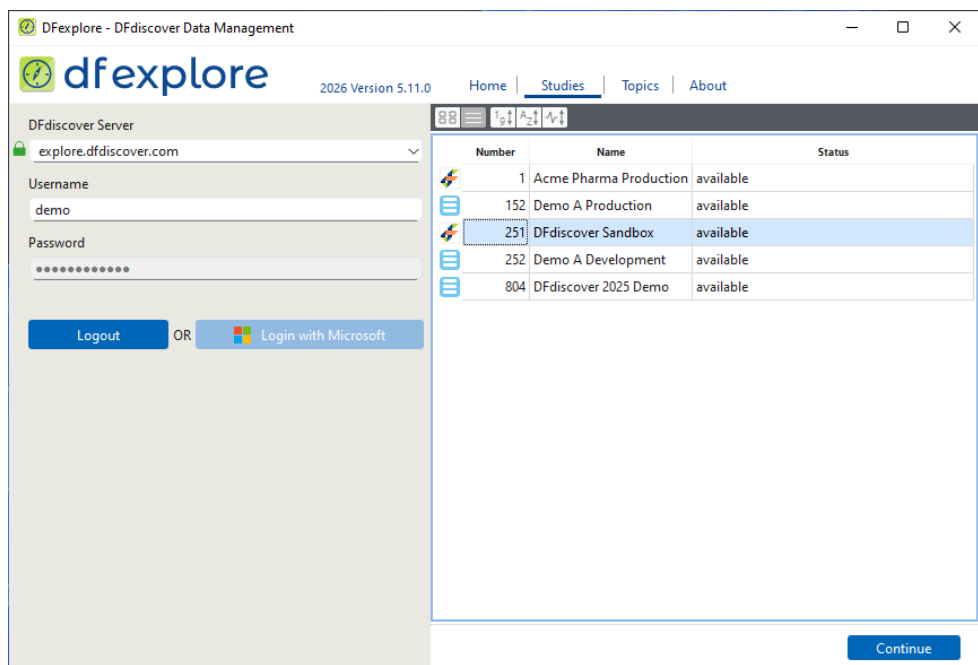
If Single Sign On with Microsoft is enabled on your **DFdiscover** server, a [Login with Microsoft](#) button will show on the login screen. If your account has been configured to use a Microsoft login, click [Login with Microsoft](#) to begin the Microsoft login process, which will open a separate dialog. Once the Microsoft login process is complete, you will be logged in to **DFExplore**.

In some cases, [Login with Microsoft](#) may be the only method of login available, depending on how the study coordinating center has configured the **DFdiscover** server.

NOTE: If you log in using a Microsoft Login, future authentication requests during your DFExplore session, such as eSignatures, will require you to authenticate using the same Microsoft login process. In these cases, click [Sign with Microsoft](#) to provide your Microsoft credentials.

Selecting a Study

After successful authentication, the study selection dialog is presented, with a list of studies you have permission to access on the **DFdiscover** server. Each study is identified by a unique number, name and current status (available or offline). If the presentation mode is study icon grid, rather than list, the current status is visible as a tooltip when hovering over the study icon.



To work on a study, double-click the study name, or highlight it and click [Continue](#).

NOTE: Your permissions may be such that you have access to exactly one study and you do not have access to [Image Router](#). In this case, the study selection step is skipped.

The user guide is available on the login screen by clicking [Topics](#) or, by selecting [Help](#) > [Topics](#) from the application menu after selecting a study. Once selected, the user guide will open in the default web browser.

User Permissions

After login and study selection, the main window of **DFExplore** is presented. You have access to only those subject records and application features that the study administrators have granted you permission to use.

Typically each participating clinical site has access to their own subjects, a subset of the available reports, possibly restrictions on which study forms can be seen, modified, printed and exported, and on which views are available.

The **DFExplore** views include:

Dashboard	show basic study metrics graphically as well as a menu of operations for commonly performed tasks
Image	enter data from new CRF images submitted by email or from DFsend (for paper-based or hybrid studies only)
Data	enter, modify and review available subject data
Queries	review and respond to questions from the study coordinating site
Reasons	review reasons provided to explain data changes or particular responses
Reports	run and review study reports
Status	review data, query and reason status by workflow levels
List	review and export data records in tabular, SAS® , and CDISC ODM-XML formats
Schedule	review visit schedule requirements and compliance
Batch Edits	run edit checks in batch to identify data issues or set data values

An overview of the **DFExplore** views makes up the rest of this tour. For more details see the chapter devoted to each view.

Dashboard View

The Dashboard View provides shortcut access for common **DFExplore** views and a snapshot summary of the current database status. It can also be customized to show other study reports.

The screenshot displays the DFExplore Dashboard View. On the left is a sidebar with navigation options. The main content area is divided into four panels:

- Record status tabular view:** A table showing counts for various record states: New CRFs (all sites) - 0, Pending records - 1, Missed records - 0, Incomplete records - 34, Final records - 100, Pending queries - 13, Outstanding queries - 20, Resolved queries - 5, Pending reasons - 7, Rejected reasons - 0, and Approved reasons - 7.
- Query category tabular view:** A table showing counts for query categories: Missing (1 Pending, 3 Outstanding, 0 Resolved), Illegal (10 Pending, 3 Outstanding, 0 Resolved), Other (0 Pending, 1 Outstanding, 0 Resolved), SDV (0 Pending, 11 Outstanding, 0 Resolved), Monitor (0 Pending, 1 Outstanding, 0 Resolved), Lab (1 Pending, 0 Outstanding, 0 Resolved), and PI Signature (1 Pending, 1 Outstanding, 0 Resolved).
- Record status chart:** A pie chart titled 'Record Status (135)' showing the distribution: Pending (1), Missed (0), Incomplete (34), and Final (100).
- Study help:** A panel providing details for 'Protocol ABCD-1234', including study objectives and site information.

View Shortcuts	In the left-hand column, shortcuts are provided for commonly accessed functionality and menu items.
Status Summary	Presented in tabular and chart forms, the status summary is an overview of the records and metadata in the current database. The table cells and chart legends are interactive and clickable.

For more details, go to [Dashboard View](#).

Data View

The components of the Data View window include the following:

- Subject Binders:** To enter or review subject data, start by selecting a subject binder from the record list panel on the left side of the main window. Binders are organized and grouped by site and then by subject within site. Each subject binder contains the data forms (CRFs) for an individual subject organized in subsections by study visit. Each subject binder has an icon, followed by a subject ID. In the example above the binder is open for subject ID 350003. You can open only one binder at a time. This locks the subject records giving you exclusive access to the binder until you close it. Subjects, visits and individual pages are color coded as follows:
 - o green - no problems
 - o red - some data problems exist
 - o orange - data entry remains to be completed
- Data Window:** The data window is where you enter data values, filling out the form using a keyboard and mouse instead of pen and paper. Data fields are color coded as follows:

- white - legal values
- red - illegal, or required but missing, values
- blue - outstanding queries, rejected reasons
- orange - query replies and reasons pending review
- green - query replies and reasons that have been approved

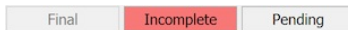
• **Queries:** Data queries can be attached to any data field, either manually or by a programmed edit check. Blue fields have one or more outstanding (unresolved) queries. Queries for the current field appear in the Query panel and the Metadata panel.

In both the Query panel and the Metadata panel it is possible to open a text window where you can answer the query. This turns the data field orange, indicating that the query has been answered and is pending review by the study coordinating site. If the reply is approved, the field is green. If the coordinating site has new questions they will revise the query and the field is again blue.

• **Reasons:** You may be able to avoid queries by entering a reason to explain an unusual data value. To add a reason to a data field, select the field in the data window and click the add button () in the **Reason for Data Value** panel. Fields with new reasons are orange to indicate they are pending review by the study coordinating site. If a reason is approved the field is green. If the coordinating site has questions they add a new query to the field and it appears in blue.

• **Missing Values:** Some studies use standard missing values, e.g. NA - not available, ND - not done, etc. which can be applied to data fields when a data value can not be entered. Each missing value has a code and a label. If standard missing values have been defined a code can be selected for the current data field by clicking in the **Missing Value** panel and choosing one. Fields with missing value codes are green and the label is displayed in the Missing Value panel when the data field becomes current. You are not able to add missing value codes to any field that has been defined as essential by the study coordinating site.

• **Saving Your Work:** After making changes to data fields, queries or reasons, you must click one of the Save buttons at the bottom of the data window to commit your changes to the central database. If you are interrupted during data entry and do not want to lose your work, you can save a partially completed page using **Pending**. If you have completed the page and there are no illegal or missing required values (red), or outstanding queries (blue) you can save your work using **Final**. Otherwise you need to choose **Incomplete**. When there are unsaved changes, one of the Save buttons is colored as a reminder of the most likely appropriate status.



Data is never stored on your personal computer, and will be lost if you do not commit it using one of the Save buttons. You are warned if there are unsaved changes and you try to move off the current page.

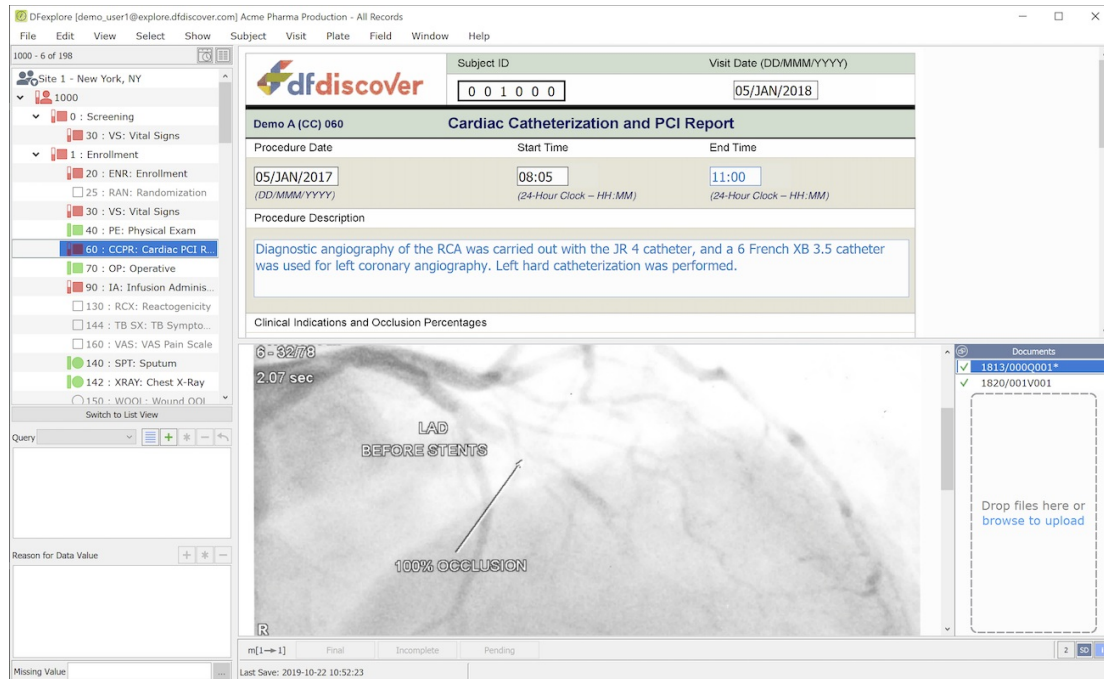
• **Last Save:** Each time that the data for a page is saved, a modification timestamp with UTC offset for that data is updated. The timestamp is stored centrally, always using the time zone where the **DFdiscover** server is located. As a convenience, the timestamp for data, queries, and reasons shown in the Data, Image, Queries, and Reasons Views is converted to and displayed in the local timezone. Elsewhere, **DFExplore** displays timestamps using the server time zone, including the Page and Field History of Changes in Data View, List View, Reports View, **SAS**® exports, etc. Before using **DFExplore**, it is extremely important that the system clock on your local computer be accurate for clock time and time zone. Data changes are always recorded using the clock and timezone of the server but your interpretation may be incorrect if the local computer clock is wrong.

• **Message Panel:** The message panel is located below the Save buttons and to the right of the Last Save timestamp. The panel displays field level help messages.

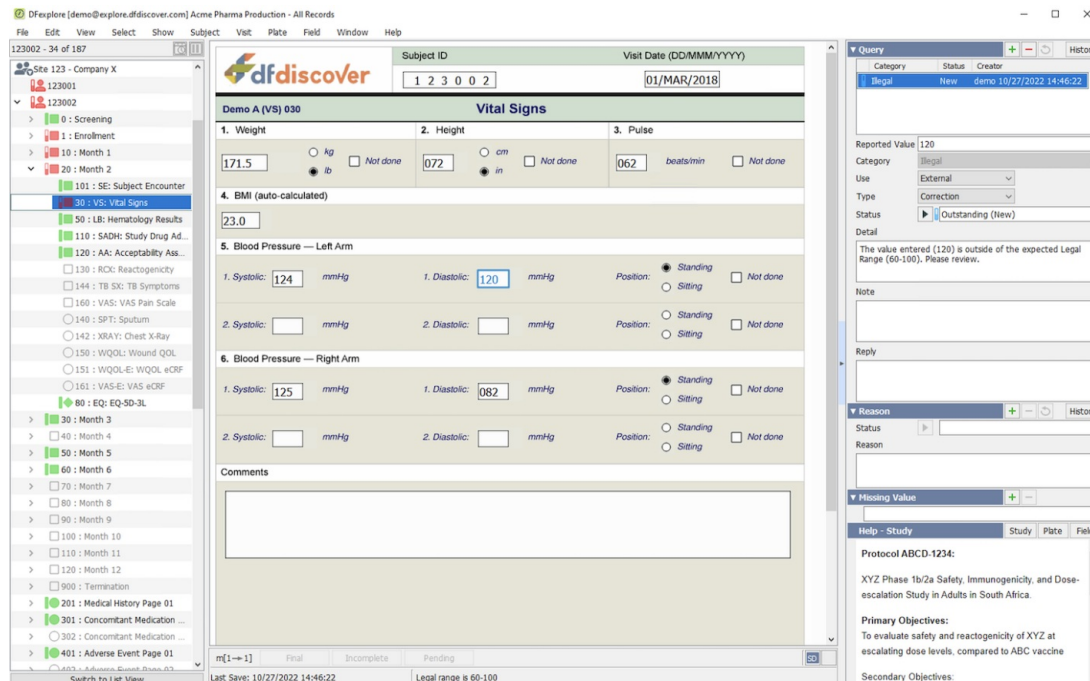
• **Images DFExplore** can store images and other supporting documents as well as data. This might include a scanned copy of a paper CRF or a medical record, DICOM video or test result. If images have been attached to the current page, the image icon () appears in the bottom-right corner of the

screen (the number and HD setting might vary according to different settings on different servers). Depending on your user preference settings ([User Settings](#)) you may need to click the image icon to toggle between data and image views. If multiple images exist, the number of images appears in a neighboring icon. Clicking this icon launches a separate window where you can review all of the images.

- **Document Panel:** DFExplore has a **Document Panel** interface available as an optional, convenience feature to aid in navigating the list of attached documents and to simplify the task of attaching additional documents, for the current page. This feature is enabled/disabled by the **Display document panel** user preference.



- **Metadata Panel:** The metadata panel is an alternative presentation of queries, reasons, missing value and help content for the current data field. It uses the entire vertical height of the main window, potentially allowing more content to be displayed. The metadata panel also offers a History button in both the Query and Reason panels, to view the history of changes to queries or reasons on the current field. User interaction with the metadata panel is the same as it is for the individual panels. Use of one panel over the other is purely a user preference.



- **Menubar:** The menus, and menu items, in the menubar differ by view and are described in the chapter devoted to each view.
- **User Preferences:** You can customize some aspects of DFExplore's behavior using the **Preferences** dialog. Once set, preferences are preserved across login sessions for the same username on the same computer.
- **Auto Logout:** To meet regulatory and subject confidentiality requirements, DFExplore was designed with an auto logout feature that closes the study connection for the current username, after a specified period of inactivity. Inactivity is measured by elapsed time during which there is no keyboard or mouse input. If this occurs when you have unsaved changes in the current data window, the unsaved changes are lost, and you will be warned that this occurred the next time you login to the study. In that event you are asked if you would like to return to the page you were on when the auto logout occurred. This simplifies the task of returning to the page but any unsaved changes cannot be recovered and will require re-entry.

Any keyboard input or mouse movement inside the **DFExplore** window resets the timer and auto logout. A default and maximum time have been configured by the study coordinating site. In the preferences dialog, you can set a different auto logout interval, but it cannot be a value exceeding the configured maximum time.

For more details, go to [Data View](#).

Queries View

The Queries View lists data queries.

DFExplore [demo@explore.dfdiscover.com] DFdiscover Sandbox - All Records

File View Show Query Window Help

Site 50 - 23 queries (3 resolved and 20 outstanding) modified between Thursday, November 7, 2019 and Friday, April 5, 2024

Site / Subject	Visit : Page	Field : Category	Status & Replies
Site 10 - New York			
Site 20 - Austin			
Site 30 - Denver			
Site 40 - Atlanta			
Site 50 - San Francisco			
50001	Day 3 : Reactogenicity	5. Size of erythema := 002.7 (Inconsistent) Detail: Please verify measurement of "2.7" cm. If correct, Item 4b "Erythema/Redness" category should be selected as "2.5-5.0 cm". Thank you!	Pending Modified by: rebecca 11/8/2019 11:31:18
50004	Day 31 : Laboratory Results- Hematology	WBC Result := 14.0 (Illegal) Detail: WBC Result has a value of 14.0, which is inconsistent with our expected legal range of 03.8~13. Please verify that this value is correct.	Outstanding (New) Modified by: rebecca 11/7/2019 14:58:30
50004	Day 31 : Laboratory Results- Hematology	WBC Clinically Significant := No (Monitor)	Resolved corrected Resolved by: laura 2/16/2023 12:00:48
50004	Termination : Study Termination	3. Termination due to an AE? := No (Monitor) Detail: Please clarify.	Pending Modified by: laura 2/16/2023 11:59:41 Replied by: laura 2/16/2023 12:00:10 Reply Text: Clarified.
50005	Day 2 : Reactogenicity	Missing Page	Outstanding (New) Modified by: mwessel 10/14/2020 14:59:59
50006	Enrollment/Vaccination #1	Overdue Visit	Outstanding (New) Modified by: laura 8/10/2023 11:06:22

You can filter the list of queries in various ways to find the ones you are interested in. For example by selecting **Show** > **Outstanding Queries** you can list just those queries that need to be answered. Double-clicking a query opens the Data View to the relevant page and puts input focus on the data field with the query.

For more details, go to [Queries View](#).

Reasons View

The Reasons View lists any reasons that have been entered to explain particular data fields.

DFExplore [demo@explore.dfdiscover.com] DFdiscover Sandbox - All Records

File View Show Reason Window Help

Site 30 - 10 reasons (1 rejected and 3 pending)

Site / Subject	Visit : Page	Field : Reason	Status
Site 10 - New York			
Site 20 - Austin			
Site 30 - Denver			
30001	Screening : Eligibility	Investigator Signature (Eligibility) : Set by DFws Import	Approved - laura_test 7/19/2022 18:24:55
30002	Enrollment/Vaccination #1 : Laboratory Results- Hematology	Lymphocytes Result : Confirmed, value is outside the legal range but correct as entered.	Pending - mark 12/8/2022 18:23:46
30002	Enrollment/Vaccination #1 : Laboratory Results- Chemistry	AST Result : Data entry error, now corrected.	Pending - mark 12/8/2022 18:24:48
30002	MH Log Page 01 : Medical History Log	Does subject have any medical history : test	Rejected - demo 11/5/2024 13:14:03
30002	MH Log Page 01 : Medical History Log	1. Medical History Term : clarified	Approved - demo 4/2/2024 15:43:22
30002	MH Log Page 01 : Medical History Log	MH Start Date 1 : test	Approved - demo 4/2/2024 15:35:07
30002	MH Log Page 01 : Medical History Log	MH Ongoing 1 : test	Approved - demo 4/2/2024 15:35:07

You can filter the list of reasons by status: outstanding, approved and rejected, and search for reasons with specified text strings. Double-clicking a reason opens the data view to the relevant page and puts focus on the data field with the reason.

For more details, go to [Reasons View](#).

Image View

The Image View is used to enter new data records from paper case report forms (CRFs) that have been submitted to the **DFdiscover** study server.

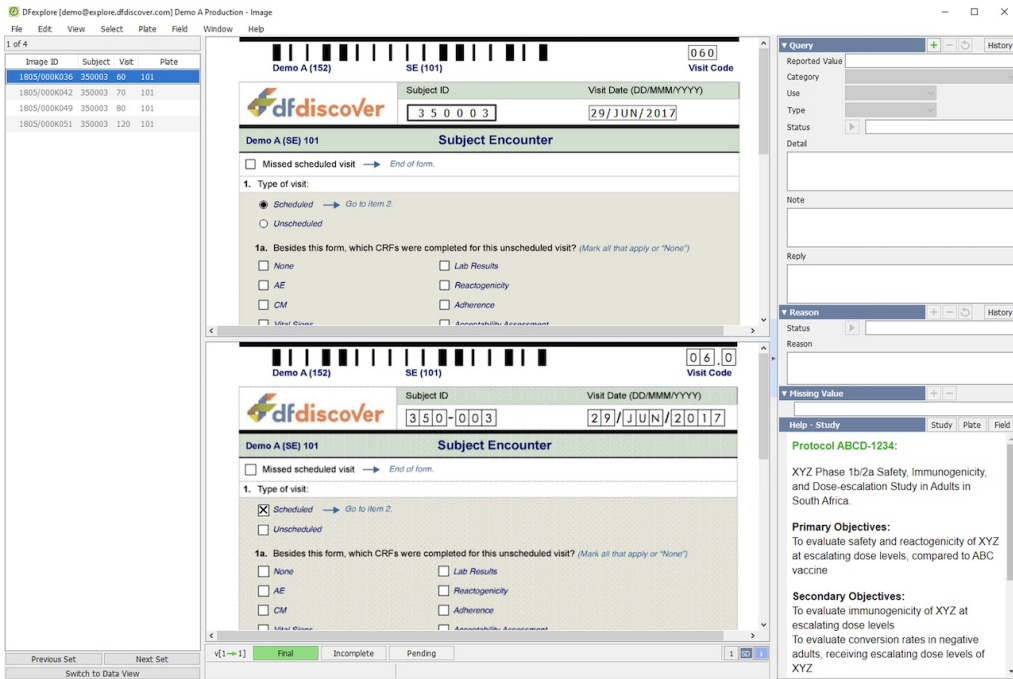


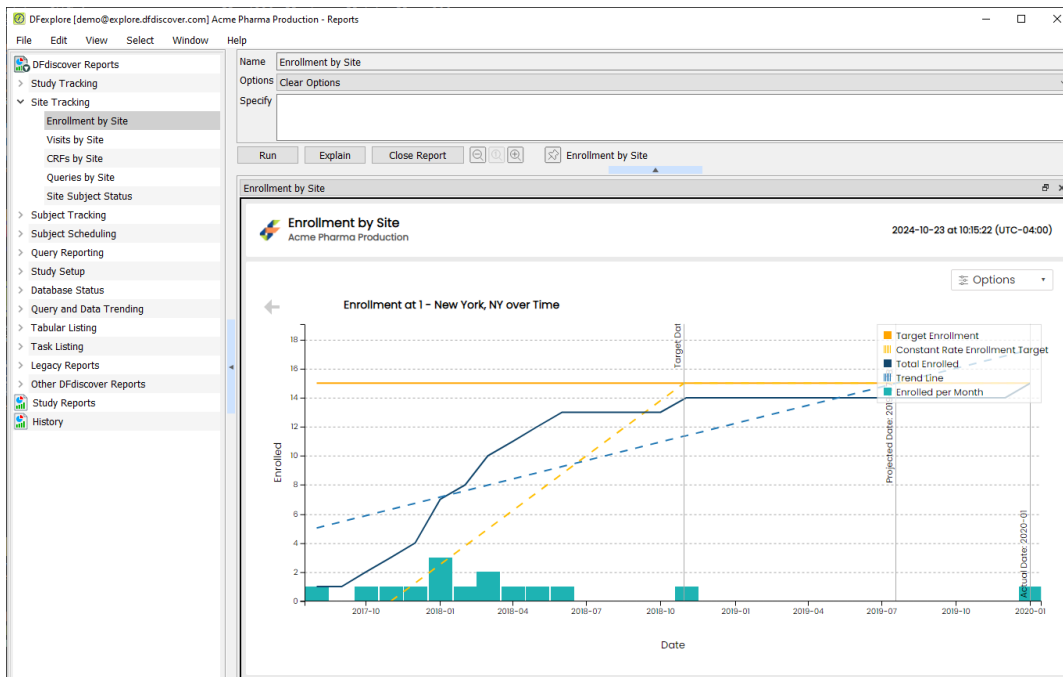
Image View is identical to the Data view except that the list of subject binders is replaced by a list of received pages that need to be entered. Image View features include:

- **Record Selection Options** Typically users chose to enter one document at a time and request the oldest ones first, but it is possible to request only certain CRF forms and to work backwards from newest to oldest arrivals. These options are specified by selecting **Select** > **Manual Retrieval...** and completing the dialog.
- **Intelligent Character Recognition:** When a CRF page arrives it is immediately scanned and read by the ICR software, preparing an initial data record for review. The task of the person using Image View is to correct any ICR errors or omissions, enter string/textual data and to add any missing value codes, reasons or queries that may be required.
- **Get **Next Set** of New Records:** When you are finished with the current set of records, click **Next Set** to release the current set of records and fetch the next set, using the selection method and criteria as previously specified.
- **Switch to Data View:** Clicking **Switch to Data View** opens the current subject binder in Data View while keeping the focus on the current page to show where it belongs in the binder. You can check other data records as needed before switching back to Image View to complete data entry for the new page.

For more details, go to [Image View](#).

Reports View

The Reports View is used to run **DFdiscover** standard and study specific reports.



- **DFdiscover Reports:** **DFdiscover** includes a number of standard reports that can be used in any study. The list of reports (which you have permission to run) appear under the **DFdiscover Reports** tab in the reports list.
- **Study Reports:** Any study specific reports created by the study coordinating site are listed under the **Study Reports** tab.
- **History:** Reports that you have already run during the current login session are saved and are listed under the **History** tab. Selecting a report from the history list displays the previous output for that report.
- **Options:** Most reports have a number of options that can be selected and are applied at the time the report is run.
- **Explain:** All of the **DFdiscover** Reports, and most Study Reports, come with a description of what they do and how to use the options. This documentation can be reviewed by selecting a report from the report list, and clicking **Explain**.
- **Run:** To run a report, select it from the report list and click **Run**. The output is displayed and added to the history list.

For more details, go to [Reports View](#).

Schedule View

Schedule View uses several tables to display available information regarding the progress of subjects through the study visitmap.

The screenshot displays the 'Schedule View' interface for a subject (ID 250001). The interface includes a sidebar with a 'Schedule and Query List' containing checkboxes for various data views. The main area is divided into several tables:

- Subject Schedule:** Shows visit details like Entry Visit, Name, Date, Days Overdue, Plate, and Last Follow-up.
- Missing and Overdue:** Lists missing pages with columns for Subject, Visit, Name, Plate, Name, Category, and Conditions.
- Visit Schedule Info:** Provides a detailed view of visits, including Subject, Visit, Name, Type, Status, Complete Date, and Schedule.
- Unexpected Visits and Plates:** Displays unexpected visits with columns for Subject, Visit, Name, Plates, Unexpected, Status, and Problem.
- Cycles:** Shows cycle information with columns for Subject, Cycle, Name, Type, Need, Status, and Terminate Date.
- Correction Queries:** Lists queries with columns for Subject, Visit, Plate, Field, Status, Category, Use, and Name.
- Cycle Visits:** Details cycle visits with columns for Subject, Cycle, Visit, Name, Type, Need, Status, and Visit Done and C.
- Clarification Queries:** Shows clarification queries with columns for Subject, Visit, Plate, Field, Status, Category, Use, Name, and Reported Value.

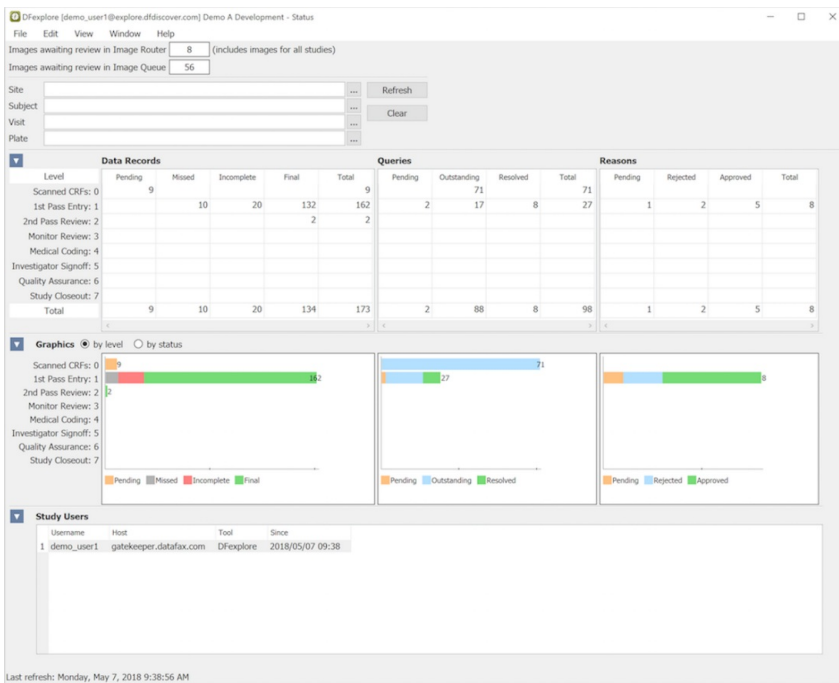
The information displayed in Schedule View depends on user permissions.

Schedule View can be used as a substitute for **DF_QCupdate** and **DF_QCreports**, providing information about missing pages, overdue visits and all unresolved, outstanding queries. Double-clicking a row in any table switches to Data View, selecting the matching record in the subject binder.

For more details, go to [Schedule View](#).

Status View

The Status View uses tables and graphs to show the number of data records, queries and reasons in the study database, categorized by workflow level and record status.



- **Permissions:** The information displayed in Status View depends on user permissions. Counts include only records that you have permission to see.
- **Filters:** The record counts can be displayed for specified sites, subjects, visits and CRF pages by entering the desired values in the filter fields and clicking **Refresh**.
- **Links:** You can jump to the data, query or reason records for any cell in the tables by double-clicking the cell.

For more details, go to [Status View](#).

List View

The List View is used to review all data records for a specified CRF plate in a table, where each column is a data field and each row is a data record.

The List View in DFExplore displays a table of data records for a specified CRF plate. The interface includes a left-hand navigation pane with a list of study plates and modules. The main area displays a table of data records with columns for Plate Number, Visit Number, Subject, Visit Date, CRF not administered, and various data fields. The table is filtered to show records for plate 110.

	Plate Number	Visit Number	Subject	Visit Date	CRF not administered	1. When was last date you took pills?	1. When was last time you took pills?	2. Did you take the tablet every day?	2a. Reported missed days	2a. Actual missed days	2b. Frequency
1	110	010	250001	01/OCT/2016	Unchecked	01/OCT/2016	09:00	No	01	01	00
2	110	010	350001	01/OCT/2016	Unchecked	01/OCT/2016	06:00	Yes			
3	110	020	350001	29/OCT/2016	Unchecked	29/OCT/2016	06:00	Yes			
4	110	030	350001	25/NOV/2016	Unchecked	25/NOV/2016	06:15	No	04		04
5	110	040	350001	20/DEC/2016	Unchecked	20/DEC/2016	06:30	Yes			
6	110	060	350001	22/FEB/2017	Unchecked	22/FEB/2017	06:00	No	03		01
7	110	070	350001	22/MAR/2017	Unchecked	22/MAR/2017	06:15	Yes			
8	110	080	350001	30/APR/2017	Unchecked	30/APR/2017	06:00	No	04		04
9	110	090	350001	26/MAY/2017	Unchecked	26/MAY/2017	06:15	Yes			
10	110	100	350001	24/JUN/2017	Unchecked	24/JUN/2017	05:45	Yes			
11	110	110	350001	22/JUL/2017	Unchecked	15/JUL/2017	05:00	No	14		14
12	110	120	350001	21/AUG/2017	Unchecked	21/AUG/2017	07:00	No	01		01
13	110	010	350003	07/FEB/2017	Unchecked	07/FEB/2017	08:00	Yes			
14	110	020	350003	05/MAR/2017	Unchecked	01/MAR/2017	09:30	No	05		05
15	110	040	350003	02/MAY/2017	Unchecked	01/MAY/2017	21:30	Yes			
16	110	050	350003	31/MAY/2017	Unchecked	30/MAY/2017	22:00	No	03		03
17	110	060	350003	29/JUN/2017	Unchecked	28/JUN/2017	23:30	No	02		01
18	110	070	350003	23/JUL/2017	Unchecked	22/JUL/2017	21:30	No	01		01
19	110	120	350003
20	110	050	450001	21/NOV/2018	CRF not administered			0			
21	110	010	450002		CRF not administered			0			
22	110	010	450003		CRF not administered			Yes			
23	110	020	450003	14/NOV/2018	Unchecked	09/NOV/2018	12:12	0	12	30	05
24	110	040	450003	08/NOV/2018	CRF not administered			0			
25	110	010	450005	01/NOV/2018	CRF not administered			0			

- **Permissions:** A plate or module is selected from the list of study plates in the left panel. Only records that you have permission to view are included, and when a record is selected, only those records which you have permission to view are shown as rows in the table, and columns are hidden for any data fields you are not allowed to see.
- **Selecting Data Fields:** Data fields (columns) can be selected and reordered using the **Select > Field Selection** dialog.
- **Selecting Data Records:** You can search for data records with specific attributes (e.g. illegal values, outstanding queries, pending reasons, etc.) using the **Select > Search** dialog.

- **Selecting Predefined Views:** Some users may have permission to define views, consisting of selected data records and data fields, for others to use. Views are created using [\[Select\]](#) > [\[Define Views\]](#) and accessed using 'Select-By View'.
- **Making Changes to Data, Queries and Reasons:** You can not modify data values, queries or reasons directly in List view. However double-clicking a data field takes you to that field in Data View where changes can be made (if your permissions allow it). To return to List View from Data View, click [\[Return to List View\]](#).
- **User Preferences:** The [\[File\]](#) > [\[Preferences\]](#) dialog includes options for customizing List View including: field color coding, displaying codes vs labels, date formats and column titles.

For more details, go to [List View](#).

Batch Edits View

The Batch Edits View provides a way for **DFexplore** users with permission to create, run and review the output from batch edit checks. This view provides a GUI to the **DFbatch** facility described in [Programmer Guide, Batch Edit Checks](#). Batch programs can be run on the server or locally (on the client's PC), with batch control files and output stored on the server or locally. In both cases, the batch view or the **DFbatch** application communicate with the **DFdiscover** server to do their work.

- **Control:** Control files can be selected from your local computer or the study server.
- **Batch:** The Batch pane is a graphical representation of a selected batch control file. Specification or editing control files in this way follows the same rules as **DFbatch** control files. This will be familiar to users that use the **DFbatch** application.
- **Output** Batch output appears in the rightmost panel in Batch Edits View. The output is presented in HTML or XML, the same as the default behavior of the **DFbatch** application.

NOTE: If you do not receive the email after waiting a few minutes, check your spam or junk folder.

For more details, go to [Batch Edits View](#).

Timestamps

Throughout DFexplore, date and time are displayed. These timestamps can reflect the server's time zone or the user's local time zone. To make the timestamps consistent, Coordinated Universal Time (UTC) offset has been added. The UTC offset for DFexplore timestamps are as follows:

Timestamp shown in user's local time

- Data View
- Image View
- Queries View
- Reasons View
- Field properties
- Metadata panels

Timestamp shown in server time

- Dashboard View
- Status View

- List View
- Reports View
- Page/Field History of Change dialogs

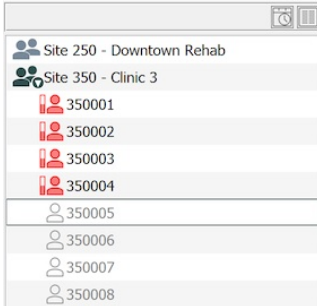
The [User Profile](#) shows the UTC offset for local and server times. The UTC offset displayed reflects daylight saving time, if applicable, for both local and server offsets.

Using DFExplore

This chapter explains how to perform a number of common data management tasks. It describes what is possible in **DFExplore**, but how these features are applied may differ from one study to another. You may receive more specific instructions from the coordinating site for your particular study.

How do I select the correct subject binder for a new subject?

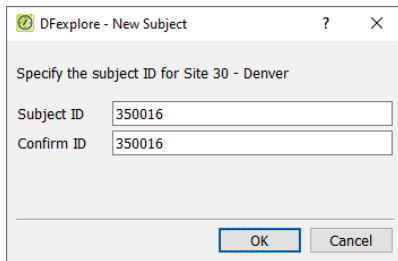
In many studies subjects are numbered sequentially as they enter the trial, but in some studies subject IDs are random and assigned on study enrollment or randomization. In either case, subject IDs must be registered in the **DFdiscover** study setup at the coordinating site before they are available in **DFExplore**.



To see the subject binders available for a site, select **View** > **Data**. If you work at more than one study site you must double-click a site to open it. Within an open site, a list of subject binders, identified by icons and subject IDs, and sorted in ascending numeric order, is presented on the left side of the screen.

Binders that are in use are represented by an active icon. Unused binders appear muted with an empty icon. In most cases, the first unused binder in the list is the correct binder for the next subject. Double-clicking the binder opens it.

If the subject ID you need is not in the subject binder list, select **Subject** > **New Subject**, and enter the subject ID number.



Enter the subject ID, and re-enter the same ID to confirm. Click **OK** to create the new subject binder. The new subject binder is added to the binder list, and this binder opens automatically.

If instead of a new subject ID, you enter one that already exists in the subject binder list, that binder opens after clicking **OK**.

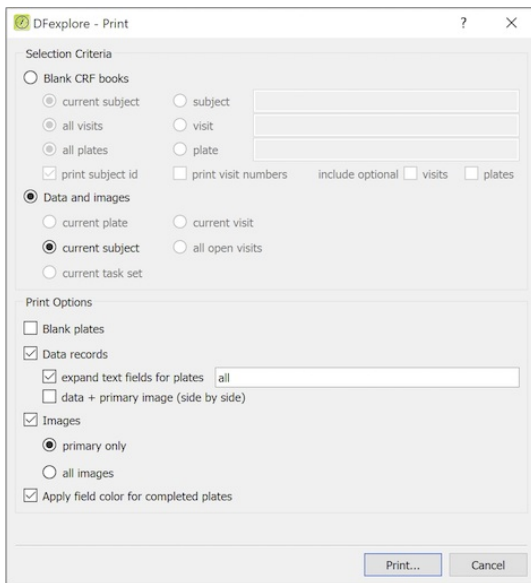
Can I print a copy of a subject binder?

Yes. You may need blank copies of the data forms to use as worksheets before entering the data in **DFExplore**, or you might complete and submit certain pages so that staff at the study coordinating site can enter the data for you. Or, you might want to print a completed visit so it can be added to the subject's medical records.

You have 2 options, with very similar dialogs, **File** > **Print** and **File** > **Save As PDF**.

To print subject CRFs:

1. Select **View** > **Data** to open Data View.
2. Open a site and then a subject binder.
3. To print only selected pages, open the corresponding visits.
4. Select **File** > **Print**.



5. Complete the **Selection Criteria** to include:

- **Blank CRF books** - CRF pages which do not yet contain data, or
- **Data and images** - completed CRF pages and their corresponding images

6. Select one or more **Print Options**:

- **Blank plates** - CRF pages which do not yet contain data, and may optionally contain the pre-printed subject ID
- **Data records** - CRF pages containing data values
- **expand text fields** - to avoid truncating long text entries and dropdown fields
- **data + primary image** - to see both the data and the supporting CRF
- **Images** - document images that exist for primary records only, or all records
- Mark **Apply field color for completed plates** to color the data fields as shown in **DFExplore**

7. Click **Print...** and complete the system print dialog.

8. In this example, the current subject is selected. **Data records** and **Images** are checked. This creates one copy of each entered page for the current subject, with data values included on pages where data has been entered. If a scanned image exists for any of the entered pages, the primary image is also included. The subject ID and visit number are printed on every page, even on blank plates. Confirm that the correct subject binder(s) is selected before printing.

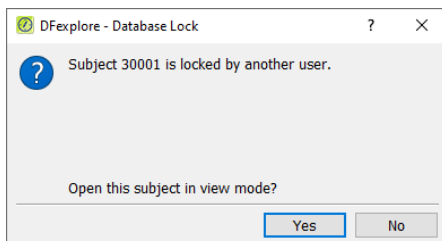
9. In this example, the current subject is selected. **Data records** and **Images** are checked. This creates one copy of each entered page for the current subject, with data values included on pages where data has been entered. If a scanned image exists for any of the entered pages, the primary image is also included. The subject ID and visit number are printed on every page, even on blank plates. Confirm that the correct subject binder(s) is selected before printing.

How do I confirm that I am the only person making changes?

DFExplore uses subject binder locking, which ensures that only one user can work in a subject binder at a time. The binder is locked when you open it and released when you close it. It is also released if your **DFExplore** session times out.

Do not lock a subject binder unless you are working on subject data or metadata. Even if you are the only person with permission to enter data into subject binders at your site, remember that someone at the study coordinating site will have permission to review, and approve or reject, new reasons for data values and replies to queries that you have entered. This too locks a subject binder until the review is completed.

If you try to open a subject binder which is locked by another user, a dialog appears asking if you want to open it in view only mode.



While in view only mode, the Save buttons are inactive and a message indicating that the subject is locked by another user is displayed at the bottom of the data window.

How can I make sure that I am completing the data forms correctly?

These are the recommended steps:

1. Double-click a subject binder to open it.
2. Double-click all of the visits that require entry/review.
3. Click the page to start on. It appears in the data window.

You can go to any page at any time by selecting it in the subject binder list. The up and down arrow keys can be used to move through the pages of all the visits that are open.
4. Press **[Tab]** or click anywhere in the background of the data window. This places the focus on the first data field and the field is highlighted.
5. Complete the first data field using the keyboard, entering text and numbers, or the mouse to select a choice option or move a visual analog slider. Choice options can also be selected using the number keys: 1=1st option, 2=2nd option, etc., and visual analog fields can also be completed by using the right and left arrow keys to move the slider along the scale.
6. As you enter values notice the field color. Required but blank fields, or fields containing illegal values, appear red and change to white when a legal value has been entered. The help message may display the legal values expected for each field.
7. After completing the field value, press **[Return]** or **[Tab]** to move to the next field. Continue in this way to complete all fields on the page. This ensures that all fields are traversed in the order planned by the form's designer. Some fields may have edit checks that are triggered as the field is entered or exited. Moving through all fields ensures that all of the edit checks are triggered, and thus that notifications of any problems are displayed.
8. Carefully review all warning and error messages displayed by edit checks. Take any necessary action to correct or explain unexpected values.
9. If necessary, move backward through fields using **[Shift] + [Tab]** or **[Shift] + [Return]**.
10. When all of the fields on the page have been completed, save your work by clicking one of the three Save buttons at the bottom of the screen:
 - **[Final]** - all fields have been completed and there are no red or blue problem fields,
 - **[Incomplete]** - a field is incomplete, or there are unresolved queries or illegal values,
 - **[Pending]** - a field is incomplete and you want to complete the page later, before it is reviewed by the study coordinating site.

Pending cannot be used after a page has reached Final or Incomplete status, and Final can not be used if the page still has problem fields.
11. Some edit checks may also be triggered when clicking **[Final]**, **[Incomplete]** or **[Pending]** to save changes.
12. If there are problem fields that you are not able to locate, select **[Plate] > [List All Outstanding Problems on This Page]**. A listing of all the problems that are preventing you from saving the page with status Final is displayed.

Resolve the problems and click **[Final]**. If some problems cannot be resolved, click **[Incomplete]**.
13. After a page is saved, the next page that is open in the subject binder list (if any) is opened in the data window, again with the focus on the first field at the top of the page.
14. Continue in this way to complete all pages in the opened visits. Those visits and pages with a square icon are required, while those with a circle icon are optional (i.e. not required for all subjects). However, an optional page may become required if some specified condition is met, thus you may find a missing page query on what would normally be an optional page.
15. Examine the icons for each completed page to confirm that each record has been saved with the correct status. Icon shape and color confirms each record status: green indicates Final status, red indicates Incomplete status, orange indicates Pending status, while any page with an outline icon has been marked Pending.
16. Double-click the subject icon to close the open subject binder. The open subject binder also automatically closes when a new subject binder is selected / opened. Remember that only one subject binder can be open at a time, and while you have it open, no one else is able to use it (except in view only mode).
17. When you are finished entering study data, or if you need to pause for more than a few minutes, exit **DFExplore**.

Do not leave your computer unattended while you are logged in to the study database.

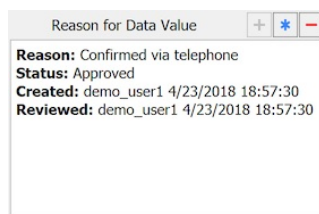
Can I enter a reason to explain an unusual value or a value that I have changed?

Yes. This is a good way to avoid queries from the study coordinating site. Add a new reason, or modify an existing reason, for any problem field (red or blue), to create a pending reason (orange) that resolves the problem, pending review by the study coordinating site. Dealing with all problem fields this way allows you to indicate that you are finished with the page by selecting **[Final]** when you save your modifications.

If there are outstanding queries on the data value, the addition of a new reason to that data value may automatically resolve one or more queries. This behavior is controlled by the "auto-resolve" attribute of each query and is defined by the coordinating site.

When a data field has the focus, all metadata (queries, reasons and missing values) for that field are shown in the metadata panels below the subject binder list.

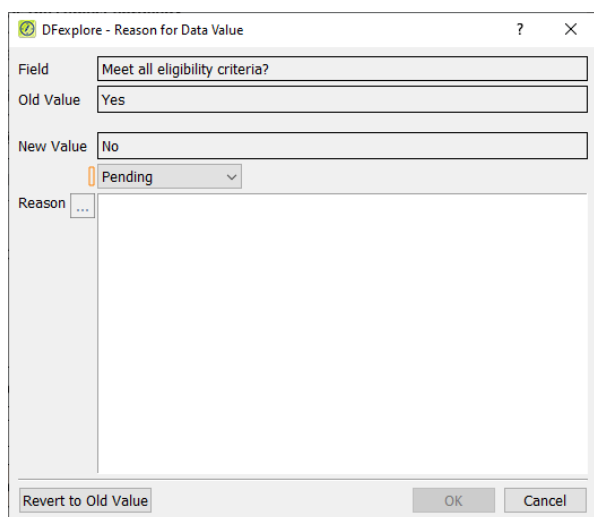
If a field already has a reason, it is displayed in the **Reason for Data Value** metadata panel; otherwise this window is empty.



The following properties are displayed:

- **Reason:** the user-specified reason for the current value in the data field
- **Status:** when a reason is created or revised its status is set to Pending. On review by central staff, status may be changed to Approved or Rejected.
- **Created:** who created or most recently revised the reason and when
- **Reviewed:** who most recently set the reason status to Approved or Rejected and when

To add a new reason, click  or select **Field** > **Add Reason for Data Value**.



The **Reason for Data Value** dialog displays:

- **Field:** The description of the current field
- **Old Value:** The value the field had when the page was opened
- **New Value:** The current value in the data field
- **Status:** The status of the reason - new reasons are created with status Pending, unless you have permission to approve reasons
- **Reason:** Enter a reason for the new value

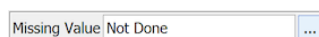
Some fields may require a reason when they are changed. In such cases the dialog appears automatically when the field is exited. You can enter a reason or click **Revert to Old Value** to undo the change. Once a reason has been entered, **OK** is used to apply it. The new reason appears in the **Reason for Data Value** metadata panel.

When a reason is created by a user who has permission to approve reasons, the status is automatically set to Approved, and **Status** is active so that the status can be changed if needed.

Remember that no reason changes are saved until the entire record is saved. This applies to all reason, query, missing value and data changes on the current record.

Can I use standard missing value codes?

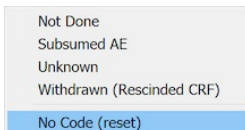
Yes. **DFdiscover** supports missing value codes. They may be predefined for each study to provide standard accepted reasons for missing data. If missing value codes have been predefined for your study, you can assign one of them to the current data field by selecting it from the list displayed when you click the button on the Missing Value metadata panel, or using **Field** > **Set Field Missing**.



When a missing value code is selected, the data field turns green (provided the field does not have some other problem) to indicate that the field has an approved metadata value. The missing value is not displayed in the data field; it appears in the Missing Value metadata panel when the field has the focus in the data window.

After applying a missing value code, the keyboard shortcut **Control** + **M** (**Command** + **M** on macOS) can be used to repeatedly apply the same missing value code to other data fields.

To remove a missing value code so that a data value can be entered, choose **No Code (reset)** from the drop-down list of missing values.



Not Done
Subsumed AE
Unknown
Withdrawn (Rescinded CRF)
No Code (reset)

What are queries and where do they come from?

Queries are questions about data values. They are always attached to a data field, manually by someone at the study coordinating site, or automatically by edit checks and other programs that check for problems.

There are 4 types of queries:

- **Data Correction Queries:** Request a correction to a data value or a blank field
- **Data Clarification Queries:** Ask for a reply to a question
- **Overdue Visit Queries:** Identify visits which should have been performed by now
- **Missing Page Queries:** Identify required pages that have not been completed

Data Correction and Data Clarification queries have several attributes - the most important is a categorical type. There are several standard categories that are always available in **DFdiscover**. They are:

- **Missing:** The field's value is blank but is required
- **Illegal:** The value is outside of the field's legal range property
- **Inconsistent:** The field's value is inconsistent with the value in another field
- **Illegible:** The source document has handwriting which is unclear
- **Fax noise:** The CRF image had transmission errors which make the page unreadable
- **Other:** An uncategorized problem described in the query details

Additionally, each individual study may define further categories for specific queries.

In some cases, such as when the category is Missing or Illegal, no further information may be needed to communicate the problem. When necessary, the query can include further details describing the problem.

If a query is attached to a data field, it is displayed in the Query metadata panel when the focus moves to that field. If the query is not yet resolved, the field is blue and the query status is Outstanding. If the query has been resolved, the field is green (unless there is another problem, like a rejected reason, or an outstanding or pending query) and the query status is Resolved.

How do I find all outstanding queries?

1. Select **View** > **Queries** to open Queries View.
2. Select **Show** > **Outstanding Queries**.

Site / Subject	Visit : Page	Field : Category	Status & Replies
Site 20 - 79 outstanding queries modified between Monday, September 23, 2019 and Tuesday, November 5, 2024			
Site 10 - New York			
Site 20 - Austin			
20002	Day 31 : Laboratory Results- Chemistry	Sodium Result := 0154 (Illegal) Detail: Sodium Result has a value of 0154, which is inconsistent with our expected legal range of 0135~0145. Please verify that this value is correct.	Outstanding (New) Modified by: rheanna 9/26/2019 09:09:23
20002	Day 56 : Subject Encounter	AE Page (1) := 04 (Inconsistent) Detail: Because 2. Were any adverse events reported? is marked 'No', AE Page (1) should not have been completed. Please clarify.	Outstanding (New) Modified by: bill 9/23/2019 14:22:03
20002	Day 56 : Physical Examination	Missing Page	Outstanding (New) Modified by: mwessel 10/14/2020 14:59:59
20002	Day 56 : Reactogenicity	Missing Page	Outstanding (New) Modified by: mwessel 10/14/2020 14:59:59
20008	Enrollment/Vaccination #1 : Laboratory Results- Hematology	WBC Result := 02.9 (Illegal) Detail: WBC Result has a value of 02.9, which is inconsistent with our expected legal range of 03.8~13. Please verify that this value is correct.	Outstanding (New) Modified by: rheanna 9/26/2019 09:10:01
20008	Day 1 : Reactogenicity	5. Size of erythema : (Missing)	Outstanding (New) Modified by: bill 9/23/2019 14:22:35
20008	Termination : Study Termination	AE Page 1 TM : (Missing) Detail: Please review. Because 3. Termination due to an AE? is marked 'Yes', AE Page 1 TM is a required field, but currently it is blank.	Outstanding (New) Modified by: bill 9/23/2019 14:24:37
20011	Enrollment/Vaccination #1 : Demographics	Missing Page	Outstanding (New) Modified by: laura 2/12/2021 09:25:38
20011	Enrollment/Vaccination #1 : Subject Encounter	Missing Page	Outstanding (New) Modified by: laura 2/12/2021 09:25:38
20011	Enrollment/Vaccination #1 : Vital Signs	Missing Page	Outstanding (New) Modified by: laura 2/12/2021 09:25:38
20011	Enrollment/Vaccination #1 : Vital Signs	Visit Date : (Missing)	Outstanding (New) Modified by: laura 2/12/2021 09:25:38
20011	Enrollment/Vaccination #1 : Physical Examination	Missing Page	Outstanding (New) Modified by: demo 11/5/2024 13:21:11
20011	Enrollment/Vaccination #1 : Injection Administration	Missing Page	Outstanding (New) Modified by: laura 2/12/2021 09:25:38
20011	Enrollment/Vaccination #1 : Reactogenicity	Missing Page	Outstanding (New) Modified by: laura 2/12/2021 09:25:38

All outstanding queries are displayed. If none are displayed you have no outstanding queries - congratulations!

- To review and respond to a query, double-click the query in the list. The main window switches to Data View, with the field focus on the data field with that query. Edit/resolve the query as required.

After you resolve a query, it is removed from the list when you return to Queries View.

How do I respond to queries?

When the focus moves to a data field that has a query, the query is displayed in the Query metadata panel.

Query Illegal (extern ·    

Category: Illegal (external, correction)
Detail: The value entered (65) is outside of the expected Legal Range (70-180). Please review.
Note: (none)
Status: Outstanding (New, in report not sent)
Created: clare 11/9/2017 13:35:50
Modified: clare 11/9/2017 13:35:50


The Query metadata window contains:

- Category:** Categorical value for the query type
- Detail:** Text description of the problem (optional)
- Note:** Optional text description to accompany a resolved query
- Status:** Current status of the query
- Created:** User that created the query and when
- Modified:** User that modified the query and when
- Resolved:** If query is resolved, user that resolved the query and when

Some queries can be resolved by correcting the data field. For example, a missing or illegal value query can be resolved by entering a legal value. In such cases the field changes from blue to green and no further action is required.

Other queries ask a question to which a reply is expected. When a reply is entered, the field turns orange (provided there are no other outstanding queries on the field) and query status changes to Pending, to indicate that the reply is ready for central review.

You can reply to an outstanding query, or modify the reply to Pending status, but you cannot change the reply once a query has been resolved.

To reply to a query, click , or select **Field** > **Reply to Query**.

The **Reply to Query** dialog includes:

- **Field:** Description of the current field
- **Category:** From one of the system types: Missing, Illegal, Inconsistent, Illegible, Fax noise, Other, or a study-defined type
- **Detail:** Optional description of the problem
- **Old Reply:** Previous reply to this query (if any)
- **New Reply:** Enter the (new) reply here


Can I respond to a query by adding a reason for the data value?

Yes, and often this will be the best response. Unless a query indicates that a reply is required, adding a reason to explain the data value is the better solution, because the reasons you enter are not changed by the study coordinating site and are thus always be visible in the **Reason for Data Value** metadata panel, whereas the current query, once resolved, may be replaced by a new query to address a new problem.

As a general rule, use reasons to explain why data fields have the values that they do, and only reply directly to queries when it is necessary to refer to other data fields, or explain something not contained in the reason.

How should I respond to a query if the data field is correct as is?

If a query asks you to correct a data value that is already correct, respond using one or more of the 3 metadata options:

- If the field is blank and an appropriate missing value code is available, choose one using the button on the **Missing Value** metadata panel. If the field is defined as 'essential', this is not possible.
- If the field is blank and an appropriate missing value code is available, choose one using the button on the **Missing Value** metadata panel. If the field is defined as 'essential', this is not possible.
- To explain why the value is correct as is, add a reason in the **Reason for Data Value** metadata panel.
- To reply to the query directly, click  in the **Query** metadata panel.

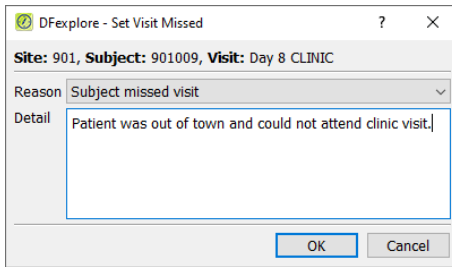
When all queries on the field have been responded to in one of these ways, the data field changes from blue to green if the response resolves the problem, or orange if the response needs to be reviewed by the study coordinating site.

Can I indicate that a subject visit is unavailable?

Yes. A subject visit might be unavailable for a variety of reasons. The subject might have missed a clinic visit or refused a particular lab test. In such cases you can indicate that the visit is missed.

To mark a visit missed:

1. Select **View** > **Data** to open Data View.
2. Double-click the subject binder to open it and display the visits.
3. Click the visit in the subject binder list.
4. Select **Visit** > **Set Visit Missed**.



In the dialog, select a reason from the drop-down list. Optionally, enter additional explanation in the **Detail** field.

- Click **OK** to save this change to the database and set the visit as missed. If an overdue visit query exists it is removed.

Once a visit has been marked missed, data entry is blocked for all pages in the visit.

Whenever a record in the missed visit is selected the reason specified when the visit was set missed appears in the Reason for Data Value metadata panel.

If you discover that it was a mistake to mark a visit missed, select the visit in the subject binder list and select **Visit** > **Unset Visit Missed...**. In the confirmation dialog, a reason is required for the change. This removes the missed flag and enables data entry for all pages in the visit.

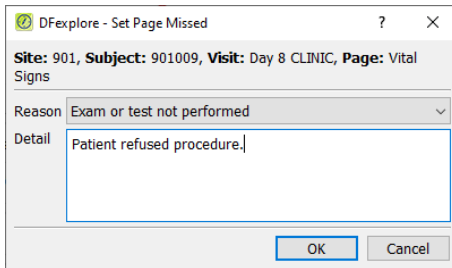
It is also possible to remove the missed attribute from individual pages by making the page current and selecting **Plate** > **Unset Page Missed...**. Again, in the confirmation, a reason is required for the change.

Can I indicate that a page is unavailable?

Yes. A single page within a visit might be unavailable while other pages can be completed. This might arise because the visit is made up of different exams and some are not relevant for some reason, or because the subject refused to complete the entire exam. Whatever the reason, individual pages can be marked missed.

To mark a page missed:

- Select **View** > **Data** to open the data view.
- Double-click the subject binder to display the study visits. Double-click the visit to open it.
- Select the page to set missed. It appears in the data window.
- Select **Plate** > **Set Page Missed...**. In the confirmation dialog, choose a reason category and enter details describing the circumstances.



- Click **OK** to save this change to the database and set the page as missed. If a missing page query exists it is removed.

Once a page has been marked missed, data entry is blocked for that page. Whenever the page is selected, the reason specified when the page was set missed appears in the Reason for Data Value metadata panel.

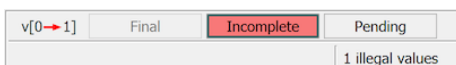
If you discover that it was a mistake to mark a page missed, select the page in the subject binder list and select **Plate** > **Unset Page Missed...**. In the confirmation dialog, a reason is required for the change. This removes the missed flag and enables data entry for the page.

Do I need to save the changes I have made?

Yes. None of the changes you make to data fields or metadata (queries, reasons and missing values) are saved until you select one of the save buttons at the bottom of the data window. The same green (Final), red (Incomplete) and orange (Pending) color coding is applied to the save buttons. Only those buttons which are valid for the current data are available.

The save buttons are:

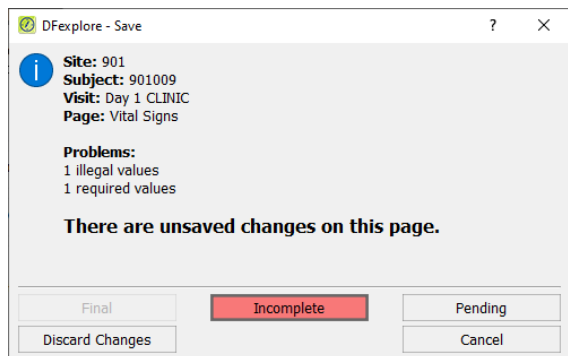
- Click **Final** if all fields have been completed or explained with reasons, all queries have been answered, and you know of no other changes that are needed to complete data entry.
- Click **Incomplete** if any field is still incomplete or any query is still outstanding.
- Click **Pending** if you are not finished with the page and would like to return to it later before it is reviewed by the study coordinating site.



There are two restrictions:

1. **Pending** is not available once a page has reached Final or Incomplete status if your permissions only allow Pending to be used during new data entry. If this is the case, **Pending** is inactive to prevent a mistake.
2. **Final** can not be used if there are any red or blue fields on the page, i.e. any problem fields which have not been corrected or addressed using a resolved query, a new reason or a missing value code). If this is the case, **Final** is inactive.

If you try to close the current page or open a different page without saving changes, a dialog appears asking if you want to save or discard your changes before opening the new page.



Click the appropriate button to continue and save your changes, discard your changes or return to the data record for further review.

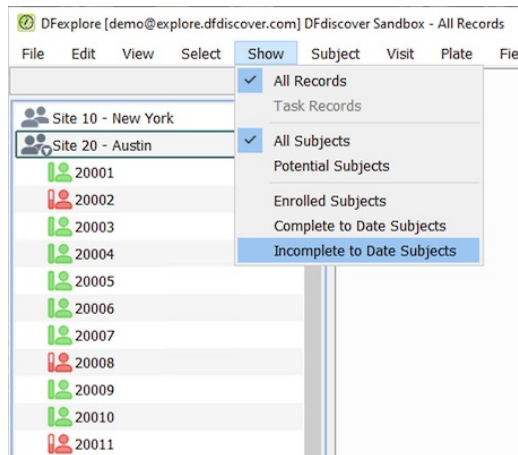
Can I undo all changes I just made to a page?

Yes, but only if you have not yet selected one of the save buttons. Select **Plate** > **Revert to Last Save...**, and click **OK** in the confirmation dialog, to undo all changes to data fields and metadata (queries, reasons and missing values). The page is returned to the state it was in when you first opened it.

This is the only undo level available. Once you have selected one of the Save buttons (Final, Incomplete or Pending), you can not revert to a previous state.



What is the best way to find all outstanding problems?

Start by reducing the subject binder list to just those subjects that have Incomplete and/or Pending pages. Select **Show** > **Incomplete to Date Subjects**.

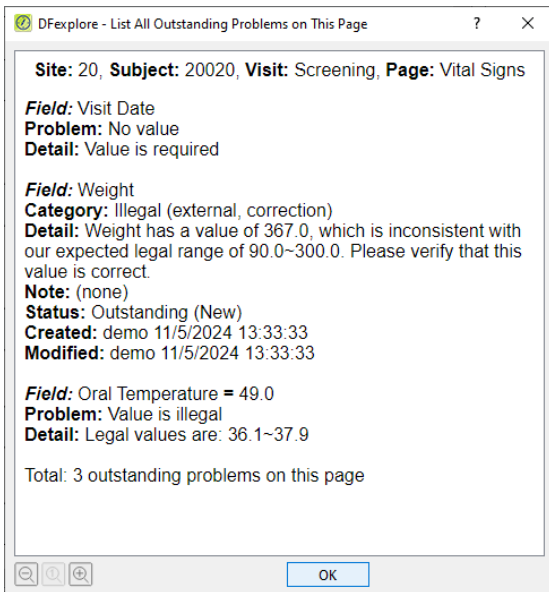


If no subject binders appear in the list, congratulations - there are no outstanding problems.

Otherwise, for each subject binder proceed as follows:

1. Open the subject binder and scan the list of visits for those which are Incomplete (red, for example ) or Pending (orange, for example )
2. When you open one of these visits, the Incomplete and Pending pages are identified with the same red and orange icons.
3. Select one of these pages and look for red and blue fields. The blue fields have metadata, either an unresolved query or a rejected reason. The red fields contain illegal values or are required but currently blank.
4. It is possible to save a page with Incomplete status even though it has no red or blue fields. This might be done when there are optional fields that still need to be completed. Users may have flagged these fields with reasons, thus it is also be a good idea to review any orange fields.
5. If you are able to resolve all problems on the page, save your changes using status Final, turning the icon color to green.

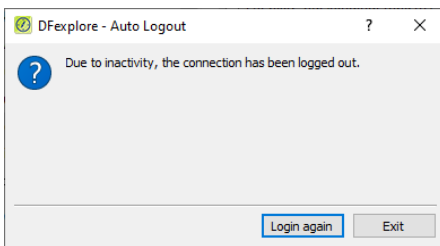
In addition to looking for red and blue fields, it is possible to get a list of all outstanding problems on the current page. To list all problems on the current page select **Plate** > **List All Outstanding Problems on This Page**.



Why did my DFExplore session Auto Logout?

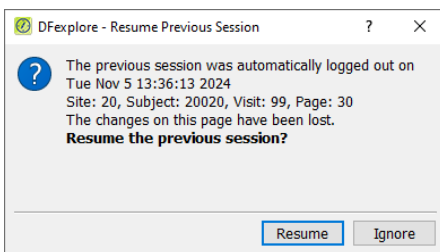
For regulatory reasons related to confidentiality of subject data and the requirement that data entry must be attributable to an authorized individual user, you must always exit **DFExplore** when your current work is done, or when you need to leave the computer unattended for any reason.

Should an unexpected event or emergency prevent you from logging out, a built-in timer will automatically log you out after a specified period of inactivity, determined by the study coordinating site.



If this occurs, any unsaved changes to the last page you were working on are not saved, and the subject binder is released so that other authorized users can access it.

If you were auto logged out from your last **DFExplore** session, you will see the **Resume Previous Session** dialog the next time you login to the same study.



The default action, **Resume** returns you to the same Data, Query or Reason view that was on-screen before the Auto Logout occurred. Click **Ignore** to return to your preferred view.

If there were unsaved changes to a page, the page is identified by subject ID, visit, and page number, and you are able to return to it by clicking **Resume**.

If you return to a page after some time has passed, and other users are authorized to modify the page, some data fields may have been changed since you last saw it. You can tell if this has occurred by comparing the time shown in the **Resume Previous Session** dialog with the **Last Save** time displayed in the data window when you return to the page.

You can change the Auto Logout timer, within limits specified by the study coordinating site, by selecting **File** > **Preferences**.

How do I exit from DFExplore?

Confirm that you have saved any changes to the page you are currently working on. If you forget you are warned when you try to exit.

When you are finished working in a study, you can close the study or exit the entire **DFExplore** session.

- To close the study connection but remain connected to the **DFdiscover** server, select **File** > **Close Study**. This takes you back to the study selection dialog.

This is a useful shortcut if you are working with **DFexplore** and multiple studies.

- To end your current **DFexplore** session, select **File** > **Exit** (Windows), or **DFexplore** > **Quit DFexplore** (macOS). This disconnects you from the **DFdiscover** server and exits the application.

What should I do if I have questions?

Attempt to find an answer within the application documentation using **Help** > **Topics**.

The study coordinating site may have also provided documentation via **Help** > **Study Help** or **Help** > **Page Help**.

If this fails to answer your question, contact the study coordinating site for assistance.

Dashboard View

The Dashboard View provides quick, convenient access to many commonly used functions. The Dashboard View can be a launching point for other views in **DFexplore**. It can further be customized to include commonly used reports, tabular and graphical summaries of the database status, and study help.

The screenshot shows the DFexplore Dashboard View with the following components:

- Data entry and review** sidebar with tasks like 'New data entry from CRFs', 'Review queries', 'Review reasons', etc.
- Record status tabular view** table:

Records	Count
New CRFs (all sites)	0
Pending records	1
Missed records	0
Incomplete records	34
Final records	100
Pending queries	13
Outstanding queries	20
Resolved queries	5
Pending reasons	7
Rejected reasons	0
Approved reasons	7

- Query category tabular view** table:

Query Category	Pending	Outstanding	Resolved
Missing	1	3	
Illegal	10	3	
Other	0	1	
SDV	0	11	
Monitor	0	1	
Lab	1	0	
PI Signature	1	1	

- Record status chart** showing a pie chart for 135 records: Pending (1), Missed (0), Incomplete (34), Final (100).
- Study help** section for Protocol ABCD-1234, XYZ Phase 1b/2a Safety, Immunogenicity, and Dose-escalation Study in Adults in South Africa.

Login and Connection Details

At the top right corner of the dashboard, two icons are displayed.

The Login Info dialog box displays the following information:

- User: demo_user1
- Email: demo_user1@myhost.com
- Server Time: 2024-02-08T16:53:36

Login Info - The first icon appears as a circle with the first letter of your username if you logged in with your **DFdiscover** credentials or as the Microsoft logo if you logged in with your Microsoft account. Click the icon to view your username, email address, and the **DFdiscover** server time at login.

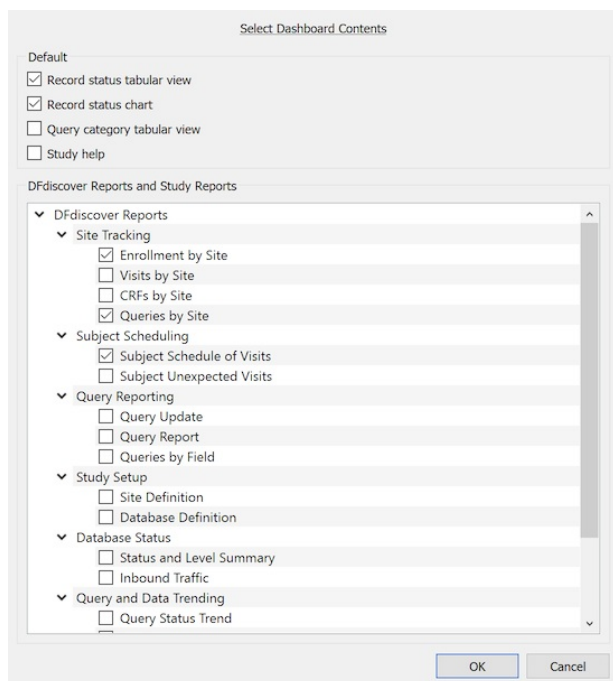
Secure Connection - Click the green lock icon to view the security protocol, cipher, and certificate information for the **DFdiscover** server.

Customize Dashboard Contents

The contents of the Dashboard View are easily customized by clicking the customize button.

A button labeled 'Dashboard' with a three-dot menu icon.

In the customize dialog, select the contents to be included in the Dashboard View. The default dashboard contents appear at the top of the dialog - de-selecting any item removes it from the Dashboard View. Any permitted **DFdiscover** or study report is also displayed and may be selected for inclusion in the Dashboard View. Reports which are not permitted, or require additional user input before running, are automatically excluded from the displayed list.



Any report can also be added by "pinning" it from Reports View, [Adding Reports to the Dashboard](#).

Any customizations to the dashboard contents are saved to the local user settings so that they are reflected in subsequent logins.

Shortcuts

A vertical column of shortcuts for commonly used menu items is presented on the left side of Dashboard View. The specific shortcuts that appear are filtered by your database permissions - your shortcuts may not match those of other users.

The shortcut for **Data View Tasks** is a pull-right menu of menu items. The included menu items are the same as the tasks that are presented when you are in Data View and access **Select** > **By Task...**

Presentation Ribbon

The main Dashboard View contains sub-windows, where each sub-window displays the output of a specific report. For optimal performance, Dashboard View limits the maximum number of sub-windows to 25 (just as Reports View does).

IMPORTANT: When there are already 25 sub-windows defined in Dashboard View attempting to add or pin an additional report will warn the user that an existing sub-window must be closed first.

The arrangement and ordering of the sub-windows is controlled by settings in the presentation ribbon.



Specifically the sub-windows can be presented in

- **Grid view** Sub-windows are organized in 2 columns (if there are at least 2 sub-windows) and as many rows as needed.
- **List view** Sub-windows are organized in 1 column with as many rows as needed.
- **Single view** Sub-windows are stacked so that one sub-window is visible at any time, occupying all of the available window space. A convenient thumbnail index and previous/next buttons are included, making it easy to navigate between single views.

To update, with current study data, the contents of all sub-windows, click the Refresh All button (). Depending upon the complexity and volume of the data request, refreshing all sub-windows may take several seconds.

Sub-window Controls

Each sub-window is a rectangular area with a body and a header. The body contains the report output. The header includes the report title of the window contents, and 3 action buttons. The action buttons, of any sub-window, from left-to-right are: close, undock and refresh the contents.



The header may also be grabbed and dragged to "undock" the window from the Dashboard View. This is similar to undocking windows in Reports View. The undocked window can be moved and positioned independent of Dashboard View. Additionally the undocked window can be "dropped" elsewhere in the sub-windows; this adjusts the layout to fill the space created by the undocked window and also creates a space to insert the undocked window in the new location.

Default Database Status Summary

By default, the dashboard includes several special status tables and graphs. These tables and graphs are special because the table cells and chart legends are clickable. Double-clicking any item builds a task to retrieve those filtered data records and presents them in Data View. Task options can be modified in the confirmation dialog before switching to Data View. If the table cell or chart legend item is related to a query, the Queries View is presented; if it is related to a reason, the Reasons View is presented.

In the table of query categories and statuses, rows are categories and statuses are columns. By default, categories (and hence rows) that have counts greater than 0 are displayed. To display all table rows, check **All** in the table header for the **Query Category** column.

To select queries for a specific category and status, double-click the matching cell in the table. To select queries for a specific category and all statuses, double-click the category label in the first column of the matching row. In the task confirmation dialog, choose if the task records are displayed in Data View or Queries View.

NOTE: When there are already 25 sub-windows defined in Dashboard View attempting to add or pin an additional report will warn the user that an existing sub-window must be closed first.

Data View


The Data View is the most commonly used **DFExplore** window. It provides access to all subject binders for data entry and review. Several of the other views provide quick access links to Data View.

The screenshot displays the DFExplore Data View interface. On the left, a sidebar shows a list of subject binders for 'Site 350 - Clinic 3', including various visits and assessments. The main window shows the 'Acceptability Assessment' for subject '350001' on '01/OCT/2016'. The assessment includes four sections: 1. Convenience (94%), 2. Swallowing (3%), 3. Side Effects (19%), and 4. Overall (95%). A 'Comments' section is also present. On the right, a panel shows query and reason details for 'Protocol ABCD-1234', including primary and secondary objectives.

Subject Binders

The Data View is organized as a list of subject binders. Subject binders are nested under clinical sites, and displayed in a list on the left side of the window. Only sites and subject binders for which you have been granted permissions are visible.


Double-clicking a site opens it, revealing the subject binders; double-clicking a binder opens it, revealing the subject visits. Visits are opened by clicking the arrow or double-clicking the visit label. This reveals the pages belonging to each visit. Only one subject binder can be open at a time, but multiple visits within the binder can be open simultaneously. Double-clicking the label for an open visit, subject or site closes it. Opening a new binder, or a new site, automatically closes the current one.





Clicking the square button () at the top of the record list panel toggles between subject binder and list navigation. In list navigation, the binders are replaced by columns showing: status icon, site, subject, visit, plate and workflow level for all records in the current subject binder, without needing to open each visit. It can also be used when working on a task set, in which case only task records are shown.

Visits and the pages within each visit are shown in visit map order, regardless of which navigation method is used.




Subject Icons

Different icons and colors indicate the status of subjects, visits and pages. Subject icons have two visual indicators, a vertical scale (rectangle) and a subject outline. The possible combinations are:

-  Subject outline, no scale - a new subject binder, not yet started

-  Green, filled scale - no problems, all pages entered so far have status final
-  Red, half filled scale - one or more pages entered so far has status incomplete
-  Orange, outline scale - one or more pages entered so far has status pending and no pages are incomplete
-  Grey, dashed outline scale - all pages completed so far have been marked missed (i.e. unavailable)

Visit and page icons use the same colors and additional scale, with the same meaning, but they come in different shapes to indicate if they are required.

-  Square - a required visit or page
-  Circle - an optional visit or page which may not be relevant for all subjects
-  Diamond - an unexpected visit or page


Metadata: Queries, Reasons and Missing Values

In addition to a data value, each field may have other information; data about the data, often referred to as metadata.

Metadata is displayed in one of two styles: bottom-left (positioned below the subject binder list) or in the metadata editor panel (right of the data window). The style used is determined by the setting for the **Display metadata editor panel** preference.

If the current field in the data window has metadata, the metadata is displayed in 3 sub-panels:


- **Query** - queries are requests for corrections or additional information from the study coordinating site. A query can be up to 500 characters long and has a status of:
 - outstanding - the query still needs to be addressed
 - pending - the query has been addressed but the solution has not yet been reviewed by the study coordinating site
 - resolved - the query has been addressed and the solution has been accepted by the study coordinating site

You can reply to a query by clicking the reply button (), entering a reply in the **Reply** field, or selecting **Field** > **Reply to Query**. After a reply is entered, the Query status changes to Pending.

There may be multiple queries on a field; if so, this will be evident from the query count on the upper-left corner of the field widget when the queried field has the focus. Use the arrow keys in the Query panel to navigate between queries and, if required, reply to each one individually.

Some queries do not require a reply and can be resolved simply by correcting the data field. A blank field with query category 'missing', or an illegal field with query category 'illegal', is resolved by entering a legal value.

If a query requests a data correction which cannot be made because the current value is correct, you can respond either by replying to the query or adding a reason to explain the current value.

- **Reason** - reasons are entered to explain unusual data values by clicking the add button (), in the Reason panel. A dialog appears where you can type a reason (500 characters maximum) or select one of the standard reasons defined for the study. For example, if a field turns red because the value you have entered is considered illegal, you could add a reason to explain the value - this might be sufficient to avoid receiving a query from the study coordinating site.

When you add a new reason, or change an existing one, the field turns orange with status pending to signal that it should be reviewed by the study coordinating site.

If you change a field that already has a reason you are required to provide a new reason explaining why the value has been changed. This ensures that the reason displayed is always related to the current value.

- **Missing Value** - if the study has been configured to use one or more predefined reasons explaining why a field has no value, you can select one of these reasons using **...** on the Missing Value window, and keyboard shortcut **Control + M** (**Command + M** on macOS) can be used to apply the most recently used missing value code to a new field. However, a missing value cannot be assigned to fields defined in the database as essential.

Data Field Colors

Colors indicate the status of data fields and whether they have associated metadata (queries, reasons and/or missing values).

The colors used for fields without metadata are:

- White - legal values
- Red - illegal values or blank, required fields

The colors used for fields with metadata are:

- Blue - fields with outstanding metadata: an unresolved query or a rejected reason
- Orange - fields with pending metadata (and no outstanding metadata): a reason or query reply that has not yet been reviewed by the coordinating site
- Green - fields with approved metadata (and no outstanding or pending metadata): a resolved query, an accepted reason, or a predefined missing value code

If more than one color might apply, descending priority order is: blue, orange, and then green.

Entering Data and Metadata

Entering data is very similar to completing paper forms, with a computer mouse and keyboard replacing pen and ink. You can go to any field by selecting it with the mouse, move to the next field using **[Tab]** or **[Return]**, or move back to the previous field using **[Shift] + [Tab]** or **[Shift] + [Return]**.

The current field is highlighted in the data window. If legal values or other help text has been defined for the current field it appears in the bottom-right corner of the **DFexplore** window.

The option to have a red asterisk display for a required field on an eCRF is enabled via Global Settings in **DFsetup**. Once enabled, if the field is required, a red asterisk (*) will be displayed near the prompt. In an eCRF table, a red asterisk will appear in a defined table header if all fields in that row or column are required. Subject ID and Visit Number are excluded as they are key fields that are auto-filled.

All entry of data values and metadata (query replies, reasons and missing values) apply to the current field. Be certain that the correct field is highlighted in the Data window before entering data and metadata. If multiple queries are present on a field, be certain that the correct query is selected by using the arrow buttons in the upper-left corner of the Query window before replying to the query.

Choice fields, which allow you to select one choice from the listed response options, are displayed with a small circle beside each option; a 'filled-in' circle denotes the currently selected option. You can select a response option by clicking the circle with the mouse, or by using the number keys - 1 for the first option, 2 for the next, etc. The current option can be removed, returning the field to blank, by pressing **[Delete]** (or **[Backspace]**).

String fields support UNICODE characters from the en_US.UTF-8 locale. During data entry, **DFexplore** blocks use of the | character - this character is reserved internally and used as the field delimiter in data and metadata records.

Saving Data and Metadata

Changes made to each page need to be saved before moving to another page. If you click a different page before saving changes, a dialog asks for confirmation to save or discard any changes before proceeding.

You can save changes to data and metadata and move the record to the save level by selecting one of the available Save buttons at the bottom of the data window.

- **[Final]** - data entry is complete; there are no outstanding problems (no red or blue fields)
- **[Incomplete]** - additional work is needed to complete this page
- **[Pending]** - use this option during new data entry to indicate that you have not finished your first pass through the page and want to complete it before it is reviewed by the study coordinating site
- **[Missed]** - this button is only available on records that have been marked 'Missed'. Use it to indicate that you have completed a task, to move the record to the save level, or to save a query that may have been added to the subject ID field.

[Missed] is the only button available if the page has been marked 'Missed'.

[Final] is unavailable if the page has any problem fields.

[Incomplete] is available even if the page has no obvious problem fields. This allows you to flag a record as needing subsequent review, regardless of the reason.

[Pending] is unavailable if the page has advanced beyond new data entry to Incomplete or Final status. Note that pending is available if your permissions include 'Data View - with select'. This permission is typically restricted to study coordinating personnel who may demote problem records to Pending status to exclude them from statistical analyses until the problem is resolved.

Electronic Signatures

You may be required to provide your electronic signature on some CRFs. When this is required, you will see one of the two following dialogs after clicking **[Final]** or **[Incomplete]** to save the CRF. Which dialog you see depends on whether you logged in to **DFexplore** with your **DFdiscover** username and password or with the Microsoft account linked with your **DFdiscover** account, if allowed on your server.

The image shows two side-by-side screenshots of the 'DFexplore - Save' dialog box. Both dialogs have the title 'DFexplore - Save' and a close button. The left dialog has the heading 'This page is eligible for signing.' and a paragraph of text explaining that entering a username and password is equivalent to a handwritten signature. Below this text is a section titled 'Enter username and password:' with two input fields: 'Username' and 'Password'. At the bottom are three buttons: 'Sign', 'Cancel', and 'Do not sign'. The right dialog also has the heading 'This page is eligible for signing.' and the same explanatory text. At the bottom, it features three buttons: 'Sign with Microsoft', 'Cancel', and 'Do not sign'.

To provide your electronic signature, enter your **DFdiscover** username and password and click **[Sign]**, or click **[Sign with Microsoft]** to provide your Microsoft credentials. If you sign multiple times within a session, after the first signature execution with both username and password, you will only need to provide your password.

Once your credentials are accepted, the eSignature fields are automatically populated on the CRF. Any changes to the data on a signed plate will remove the

eSignature (by blanking the eSignature fields) and will again require signing by an authorized user when the CRF is eligible for signature.

If your credentials are not accepted, you may retry a limited number of times. Multiple consecutive attempts to sign with invalid credentials will cause the signing to fail and your login session to be ended. A notification email will be sent to the **DFdiscover** server administrator.

Correcting Key Fields

Each data record has 4 numeric key fields: Study, Page, Visit and Subject. Together they uniquely identify each data record in the study database. It is critical that these keys are correct. In most instances they are automatically set to the correct values.

If you discover an error in one or more keys, it can be corrected by selecting **Plate** > **Change Keys** and correcting the values in the dialog.

DFExplore - Change Keys

This page belongs to a different study

Study
Change from 252 to

Page
Change from 020 to 020 ...

Visit
Change from 1 to ...

Subject
Change from 250001 to

Reason

OK Cancel

The study number can only be changed if the data record has an image. When the study number is changed all images are sent to the router and the data record is deleted from the current study. It is not possible to move a data record directly to another study even if you have the necessary permissions.

Changing any or all of the other 3 keys (page, visit and subject) moves the data record to another location in the current subject binder, or to another subject binder. All queries, reasons and images move with the data record.

A reason may be specified to explain the change. This is recommended, but is optional.

Click **OK** to confirm the change. Checks are conducted to confirm that the new plate is compatible with the old one. An additional check is performed to determine if a data record with the new keys already exists in the database. Depending on the result of these two checks, one of the following confirmation dialogs is presented:

- **No existing record but pages are not compatible**

DFExplore - Change Keys

i The following is specified to change:
- the subject from **250001** to **250002**

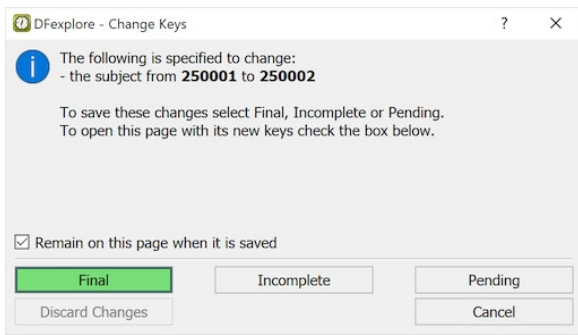
To save these changes select Final, Incomplete or Pending.
To open this page with its new keys check the box below.

Remain on this page when it is saved

Final Incomplete Pending
Discard Changes Cancel

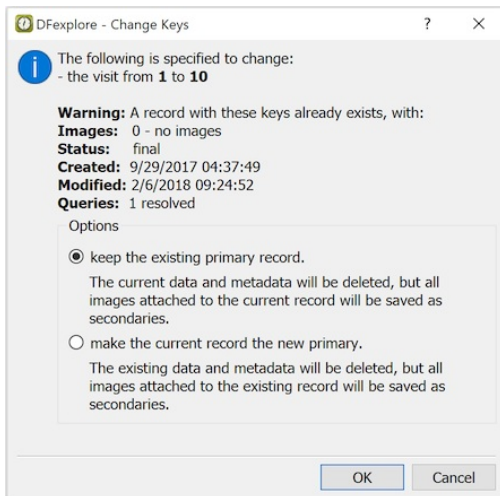
If the new page has different data fields from the old one, the existing data, queries and reasons can not be transferred and must be discarded. In this case a warning message is displayed. Click **Cancel** if you do not wish to continue, or choose a save option to proceed with the key change. If you check **Remain on this page when it is saved**, the page opens in it's new binder location. This is recommended.

- **No existing record and pages are compatible**



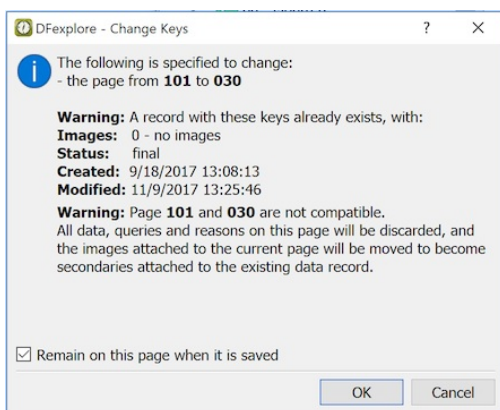
In this example, only the subject ID is being changed. Since the pages are the same they have the same data fields and thus it is possible to transfer the data record to the new keys. Click **Cancel** if you do not wish to continue, or one of the Save options: **Final**, **Incomplete** or **Pending** to proceed with the key change.

- **New keys already exist and pages are compatible**



If a data record already exists with the new keys you can either cancel the key change or continue by selecting one of the two conflict resolution options. If you chose to keep the existing primary record it is not changed in any way, and the current data record with all of its queries and reasons is deleted. The only thing that moves to the new keys is any images from the current page. If you chose to make the current record primary, it is moved with all of its queries, reasons and images to the new keys, and the existing data record with all of its queries and reasons is deleted. Images only are preserved from the existing record and they become secondary.

- **New keys already exist but pages are not compatible**



If a data record already exists with the new keys, and the data fields on the current page differ from those on the existing page, you can either cancel the key change or continue. If you chose to continue, the existing data record is not changed in any way. The data on the current page cannot be moved because the data fields are different on the new page, thus all data, queries and reasons on the current page are discarded. The only thing that moves to the new keys is any images from the current page; and if the existing page already has images, all moved images become secondary.

Images of CRFs and other documents

DFdiscover can receive scanned, faxed or otherwise generated images and link them to data records. An image can be a scanned copy of the original paper case report form, a supporting source document from medical records (i.e. DICOM), or other audio-visual files generated by medical imaging devices. The image or supporting document can be in landscape or portrait orientation.

Each image or supporting document must be linked to one and only one data record. Images such as video files or multi-page documents are displayed with

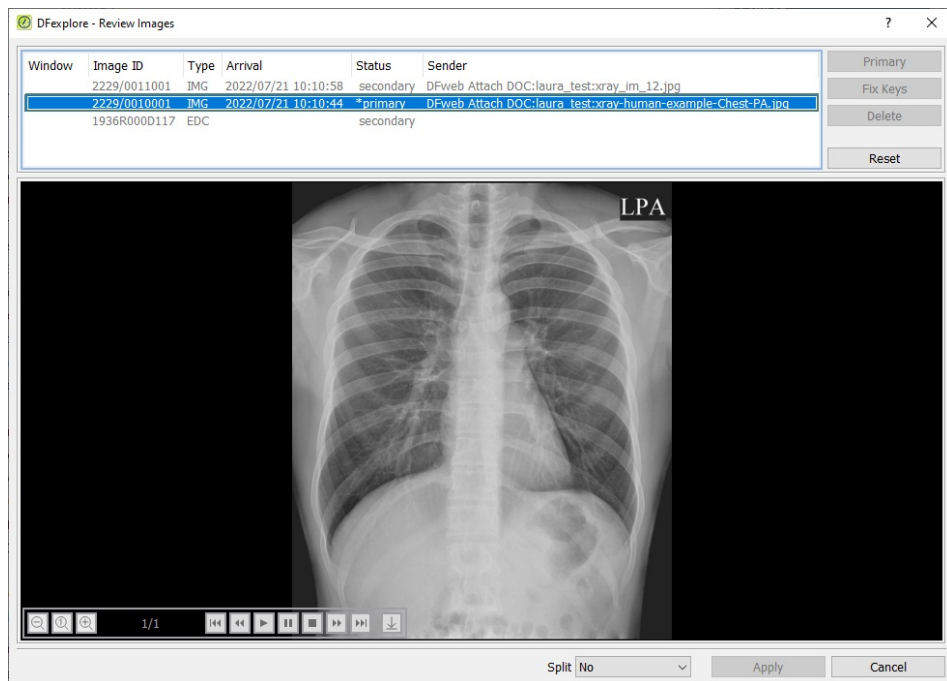
controls that permit playing the file or navigating the document.

Multiple images or documents may be linked to the same data record (e.g. all scanned copies of the original CRF page as corrected over time). One image must be designated as the 'primary' copy. This is the image or document that appears along with the data record when the screen is split in data and list views. All other images are designated as 'secondary'. They are reviewed by selecting [Plate] > [Review Images] or clicking the image counter (2) in Data View.

Image Option Buttons

If one or more images have been linked to the current data record, two additional buttons appear with the image counter, 2 SD I. Clicking the image button (I) toggles visibility of the primary image. The behavior varies depending upon the setting for **Image Window : Display method** in the [File] > [Preferences] dialog.

The first (left-most) button reports the number of images linked to the current data record. Click this button, or select [Plate] > [Review Images], to access the **Review Images** dialog.



This dialog shows all images linked to the current data record. It shows each Image ID, image Type, Arrival (when the image was received), Status (whether it is the primary or a secondary image), and the Sender (identification of the sender). This dialog is used to:

- **Review Images:** Select any image from the image list to display that image.
- **Split:** The drop-down has 3 choices: No, Top-Bottom and Left-Right. When the window is split, click any 2 images in the image list to display them together. Double-clicking one of the images in the image list switches them between the two display windows.
- **Specify the Primary Image:** When the dialog opens the primary image is tagged with an asterisk (*) in the image list. Selecting a secondary image and clicking [Primary] changes that image to primary and demotes the original primary image to secondary. The asterisk however remains on the original primary image as a reminder of which image was primary when the dialog was opened. Changes in image status do not take effect until [Apply] is clicked.
- **Delete Images:** Select an image and then click [Delete] to change Status to 'deleted' (this does not take effect until [Apply] is clicked). Status can be changed from 'deleted' back to 'primary' or 'secondary' by clicking [Undelete]. Once [Apply] is clicked this is no longer possible. If there is more than one image, the primary cannot be deleted until all secondary images have been deleted.
- **Fix Keys** If an image has been linked to the wrong data record you can re-link it to the correct record by clicking [Fix Keys] and entering the correct subject ID, visit and/or plate numbers. The image is unlinked from the current data record and linked as a secondary image to the data record of the new keys. If necessary, the new record can subsequently be opened to change the image status from secondary to primary.

High Definition (HD) Images Setting

For documents that are transmitted and received with quality settings higher than black-and-white image quality (grayscale and color PDFs for example), it is possible to also locally view such documents using HD mode in **DFEExplore**.

The default is to view images at standard definition (SD), which is equivalent to historical black-and-white, 100 dpi image quality. The central data management office can enable HD images (300 dpi) to be received for a study via **DFAdmin**. Individual users can determine if they wish to view the HD images in **DFEExplore**, if it is available.

To enable the HD setting in **DFEExplore**, toggle the SD button SD at the the lower-right corner of the the screen in Data View, which changes to: HD. If there is an HD version of the image available, the screen refreshes with the HD image. If HD is not enabled at the study level or an HD image was not transmitted, the SD/HD toggle changes to SD to indicate that there is no HD version of the image available: the HD setting is enabled but the SD image is displayed.

Like other screen settings, the HD setting is stored locally in your device-specific settings. For example, this allows you to easily work over a slower laptop

connection with HD mode disabled. HD mode can be enabled on another device (an office computer perhaps) which has a fast internet connection.

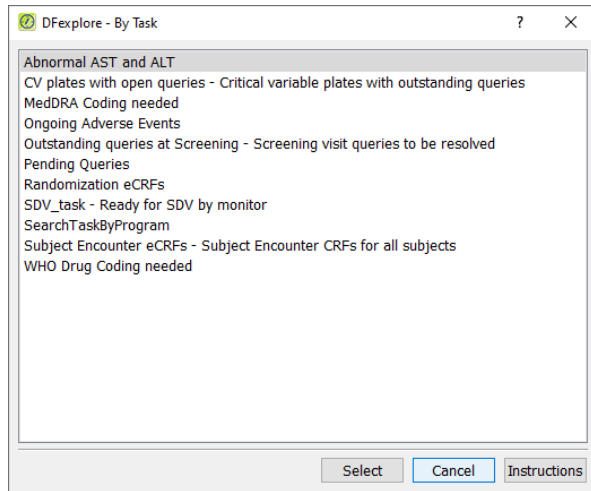
Working with Tasks

Tasks, which are user instructions and record retrieval specifications, can be defined and assigned to individual users or study roles. Any user with access to Data View can perform tasks. However, 'Data with Select' permission is required to define tasks.

It is also possible to export and import tasks, even from other studies. The export dialog is a standard dialog that simply prompts for a file name using either .dat or .txt file name extensions. The import dialog is an extension of the task definition dialog that allows selection and import of a previously exported task definition as a starting point for the new task definition.

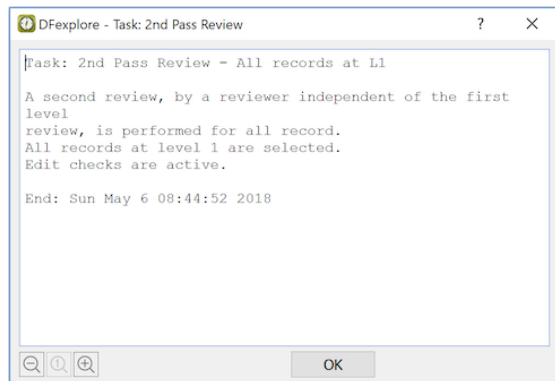
Performing Tasks

To perform a task, select **Select** > **By Task**. Alternatively, use the **Data View Tasks** pull-right from Dashboard View.



Only tasks assigned to your login or study role are listed in this dialog.

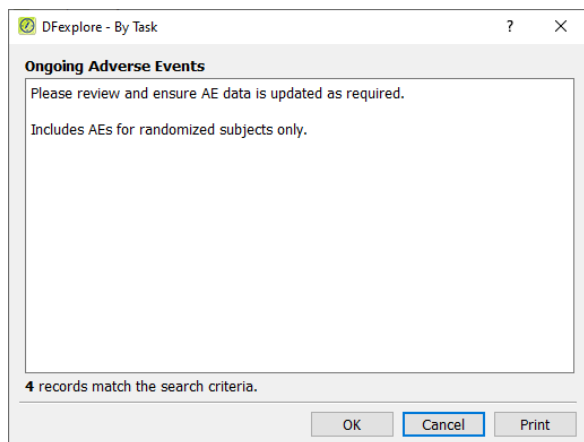
If available, task instructions can be viewed before starting the task by clicking **Instructions**.



Instructions are specified when the task is created, and can subsequently be modified.

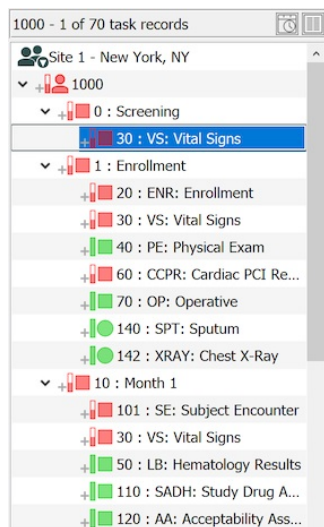
To perform a task, double-click it in the list, or highlight it and click **OK**.

After selecting a task, a confirmation dialog with the task instructions (if available) and the number of records matching the task criteria is displayed.



Confirm the retrieval by clicking **OK**.

The subsequent task record list includes those records (sites, subjects and visits) with matching task criteria. If your user preference **Open first task record when task set is built** is enabled, the first task record opens automatically; otherwise a subject binder must be selected to display the task records.



The title shows the current subject ID, the current task record and the number of task records for this subject.



Task records are flagged with a plus symbol () which changes to a checkmark () when the record is saved, indicating that the task for that record has been completed. The current record counts are displayed at the bottom of the **DFExplore** window (Task: 1/35).

Click **Show All Records for This Subject** to open the subject binder and review other records for the current subject. Click the button again to return to Task Records only.

More than one user can work on the same task at the same time. Each user gets a list of pointers to the records currently available for the task, but a subject binder is locked only when it is opened, and only one user can have the binder locked at a time. Other users are able to open the binder in view only mode until the lock is released.

Saving a task record changes the task icon from to , but only for the user who saved the record. Thus if more than one user is working on the same task at the same time, it is possible that the task has been completed by one user before another user opens the subject binder, and that the second user may wonder why the record has been included in the task set. A clue that this may have occurred is provided by the value for **Last Save** at the bottom of the screen - it may indicate that the record has been modified since the user began working on the task.

When you are finished performing a task, select **Select** > **All Records** to dismiss the task set. This removes the icons from task records, and resumes access to all subject binders and data records.

Defining Tasks

Tasks are used to open a set of data records based on pre-defined criteria. Users with permission can define tasks for themselves and other users using the task definition dialog. This dialog is available by choosing **Select** > **Define Tasks**. Only one user can define tasks at a time, but other users can open this dialog in view only mode.

Task definitions have the following properties:

- **Task name, Description and Instructions** document the meaning and purpose of the task. All three are displayed to tasks users. Use instructions to provide additional context for what is expected from the person reviewing the task.
- **User Role and Username** identify who is allowed to perform the task. This task will only be available to those whose username or role is defined here.
- **Owner Role and Username** identify who is allowed to modify the task definition. In addition, study administrators have permission to modify all tasks.
- Specify a **Mode** and **Save Level** to indicate how each record level should be updated. Mark **Enable edit checks** to indicate that edit checks fire (or not) when the task records are retrieved and traversed.

Save Level is a number (1-7) that is stored as a special field (DFLEVEL) in each data and metadata record for workflow management. New data entry is typically saved at level 1. Higher levels are used to indicate that some review task has been completed - analogous to moving paper CRFs from one person's inbox to another.

For detail about the available Modes, see [Changing Mode and Level](#). When defining tasks for use in **DFweb** and **DFcollect**, note that view, edit, modify, and validate modes are supported, but DDE mode is not supported in **DFweb** and **DFcollect**.

- Use the **Search** section to define what records are retrieved. The search can be performed by data, query or reason criteria, or by program. Simple criteria such as site number, subject, visit or plate number(s), workflow level, and creation/modification date(s) may be used. Hover over the field for each option to view the format required for each field. More complex search criteria is also supported with the following options:
 - **Subject** Click next to the **Subject** field to open another dialog for [Selecting Subjects based on Criteria](#), which implements subject selection based on multiple criteria across multiple plates.
 - **Pattern**: Search for a specific text string. This search is case sensitive.
 - **Expression**: Click next to the **Expression** field to open another dialog for [Expression Editor](#), which uses simple algebraic statements to describe the desired data records. This option is only available when a single plate is specified.
 - **By Program**: Perform more advanced searches by using a standard or custom program, as described in [Task Definition by Program](#).

Multiple user and owner roles, and usernames, may be entered using a comma delimited list.

Task ownership specifications are ignored for study users with **DFdiscover** or study administrator privileges. These special users can view, edit and delete any task including those created by other users.

The task set returned to each user depends on their role permissions, and equals the intersection set created by the task retrieval criteria and the user's permissions. Thus it is not possible to grant extra permissions to a user within a task definition. For example, one task can be defined and used by all of the clinical sites because each site receives only the data records they are allowed to see.

Task Definition Examples

This section includes several example task definitions. These examples illustrate how data, query, reason and program criteria are used to define the records to be selected for different tasks.

Example Review Task for drug coding

This example illustrates a review task for drugs recorded on plate 300 currently at workflow level 3. Subject selection criteria (not shown here but indicated by 'use subject from criteria' in the Subject field) has been used to select records where the 'check if none' data field (MEDNONE) is empty (code 0) because we only need to review pages on which drugs have been recorded.

The screenshot shows the 'DFxplore - Define Tasks' dialog box. The 'Task' field is 'WHODrug Coding'. The 'Description' is 'Review and code medications'. The 'Instructions' are: 'Concomitant Medication pages at level 3 are selected if "yes" is marked for "Any medications to report?" Review medication matches and code non-exact matches. Edit checks are active.' The 'User Role' is 'Coder', 'Username' is 'demo_user1', and 'Owner Role' is 'demo_user1'. The 'Created' date is '2018-05-07 11:30:34' and 'Modified' is '2020-06-16 15:38:50'. The 'Mode' is 'Validate' and 'Save Level' is '4 - Medical Coding'. The 'Search' options are 'Data', 'Query', 'Reason', and 'By program', with 'Data' selected. The 'Status' options are 'Final', 'Incomplete', 'Pending', and 'Missed'. The 'Subject' is 'use subject from criteria'. The 'Visit' is '300', 'Plate' is '3', and 'Level' is '3'. The 'Creation', 'Modification', 'Pattern', and 'Expression' fields are empty. Buttons at the bottom include 'Save', 'Done', 'Open Task', 'Clear', and 'Cancel'.

To be selected, records must meet all of the specified criteria. The task is performed in Validate mode with edit checks turned on. Each saved record has its save level raised from 3 to 4.

Example Query Review

This example illustrates a task for someone who reviews new queries created by data entry staff during new data entry at level 1, to make sure they are clear and appropriate before being sent to the clinical sites in a Query Report.

The screenshot shows the 'DFxplore - Define Tasks' dialog box. The 'Task' field is 'New Queries'. The 'Mode' is 'Validate' and 'Save Level' is '2 - 2nd Pass Review'. The 'Search' options are 'Data', 'Query', 'Reason', and 'By program', with 'Query' selected. The 'Site', 'Subject', 'Visit', 'Plate', 'Field', and 'Level' fields are empty. The 'Level' field contains '1'. The 'Creation', 'Modification', and 'Resolution' fields are empty, each followed by a 'By' field. The 'Pattern' field is empty. The 'Detail' field contains 'Criteria have been specified'. Buttons at the bottom include 'Save', 'Done', 'Open Task', 'Clear', and 'Cancel'.

This task should be performed using the **Field** > **Review Queries & Reasons** dialog so that queries can be saved on their own, raising them to level 2 without changing the workflow level of the data records.

The additional **Query Detail** dialog is used to specify the unique query criteria.

Example New Reasons Review

New reasons entered to explain data values are set to status Pending with the expectation that they are reviewed and either approved or rejected, along with a query explaining why and requesting a correction or additional information.

Task records = all data records with reasons that have status Pending. Mode is set to Modify and the sign off level is set to 2. We could also have used Edit mode which would leave the reasons at their current workflow level.

This task could also be performed using the `[Field] > [Review Queries & Reasons]` dialog.

Task Definition by Program

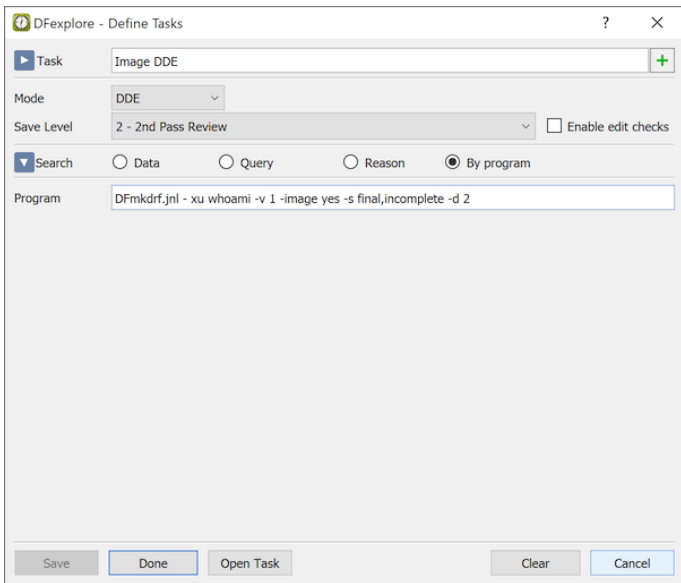
The following examples illustrate how tasks can be defined by running a program that generates a data retrieval file as output.

DFdiscover includes 2 standard programs which are designed for this purpose: *DFmkdrf.jnl*, which selects records from the study journal files (audit trail), and *DFmkdrf.ec*, which selects records identified by edit checks. A few examples are shown here. A full description of these programs can be found in [Programs](#).

Custom programs may be also developed for this purpose. They must be stored in the study *ecbin* directory and must generate a data retrieval file as output. If you need to write a custom program, an explanation of data retrieval files can be found in [Programmer Guide, Data Retrieval Files \(DRF\)](#).

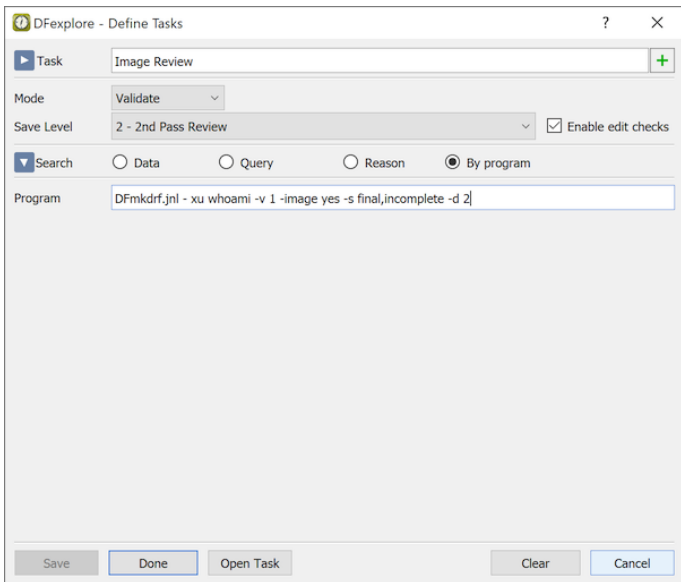
Example Image Review with Double Data Entry

example-contents In this example, double data entry (i.e. Mode=DDE) is performed on data records saved by other users (-xu whoami) with associated images (-image yes), which were at level 1 (-v 1) with status final or incomplete (-s final, incomplete) at any time during the study, and still meet these criteria today (-d 2).



Example Image Review without Double Data Entry

Instead of performing double data entry, it may be considered adequate to review level 1 data entry records and move them to level 2. If so, the same retrieval criteria can be used with Validate instead of DDE mode.



Example Search for Today's Records

Users sometimes forget exactly what case they were working on earlier in the day but want to retrieve it so they can check something or make a change. With no deselection (-d) option specified, records are retrieved even if subsequently saved today by someone else.

DFxplore - Define Tasks

Task: Today

Mode: Edit

Save Level: 1 - 1st Pass Entry Enable edit checks

Search: Data Query Reason By program

Program: DFmkdrf.jnl -u whoami -t today

Buttons: Save, Done, Open Task, Clear, Cancel

Task Definition by Edit Check

The edit check programming language gives the programmer access to all data fields for all plates, visits and subjects, and includes functions that can be used to test for the existence and status of queries and reasons. Thus it is ideally suited for the definition of tasks that involve complicated record retrieval criteria. All the programmer needs to do is raise a message using `dfwarning` or create a query using `dfaddqc` on records that are to be selected, and use function `dfbatch` if the edit check is to be executed only when the task is being performed.

Example Search by All Edit check Results

This task runs all edit checks (-E ALL) on plate 1 (-P 1) data records that are currently at level 1 (-v 1). No edit check actions are applied. Instead records are retrieved if one or more edit checks would have added a new query, modified an existing query, displayed a message, or changed a data field.

DFxplore - Define Tasks

Task: Edit Checks (Screening)

Mode: Validate

Save Level: 2 - 2nd Pass Review Enable edit checks

Search: Data Query Reason By program

Program: DFmkdrf.ec -P 1 -E ALL -v 1

Buttons: Save, Done, Open Task, Clear, Cancel

Example Search by Specific Edit check Result

In this example the edit check (-E CheckInit) is programmed to check subject initials and display a warning message if they differ from some reference value. In this task, the edit check is run on all pages used in the study (-P 1-102) and thus retrieves all records on which this message would be displayed.

DFExplore - Define Tasks

Task: Edit Checks (Initials) +

Mode: Edit

Save Level: 2 - 2nd Pass Review Enable edit checks

Search: Data Query Reason By program

Program: DFmkdrf.ec -P 1-102 -E Checkinit

Buttons: Save, Done, Open Task, Clear, Cancel

Example Search by Custom Edit check

The following example shows how an edit check could be used to find unusually large changes in diastolic or systolic blood pressure between visits. It could be programmed to add a query if a suspicious change is found, and to do nothing if a query for this category has already been added to the blood pressure field in question.

DFExplore - Define Tasks

Task: Edit Checks (BP Review) +

Mode: Validate

Save Level: 3 - Monitor Review Enable edit checks

Search: Data Query Reason By program

Program: DFmkdrf.ec -P 5 -E CheckBP -S 21-24 -v 2

Buttons: Save, Done, Open Task, Clear, Cancel

In this example edit check (-E CheckBP) is triggered on page 5 (-P 5) at all follow-up visits (-S 21-24) which are currently at level 2 (-v 2).

By running this edit check in a task, you can review the blood pressure readings recorded on the submitted CRF pages and verify that any unexpected changes are not the result of data entry errors.

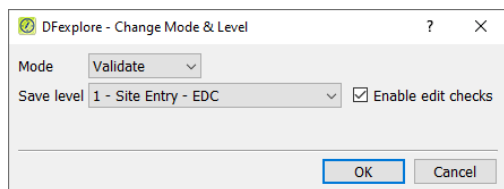
Ad hoc Record Selection

In addition to using predefined tasks to select data records and set workflow modes and levels, users who have Data with Select permission can perform ad hoc retrievals using the same search criteria used to define tasks. Working in this way requires an understanding of the study workflow plan and is thus most appropriate for central data management staff. This permission typically is not enabled for clinical sites and thus the features described here may not be available to all users.

Changing Mode and Level

DFExplore allows you to work in 5 different modes and to keep track of data reviews and other tasks by moving records from one workflow level to another when a task has been completed.

The default mode, defined when **DFExplore** starts, is Modify and the default save level is set to your lowest write level (defined in your study roles). Mode, save level, and whether edit checks are enabled, are also set whenever you perform a task or build an ad hoc task set. They can also be changed at any time by selecting [\[Select\]](#) > [\[Change Mode & Level\]](#).



The choices for **Mode** include:

View	No changes can be made to data or metadata, and no changes are made to the workflow level.
Edit	Changes can be made to data and metadata (as permitted by user permissions). New and modified metadata are saved at the current level of the data record, and the level of the data record itself remains unchanged.
Modify	The workflow level is changed to the specified Save Level, only for those data and metadata records that are modified. It is possible for data and metadata records to end up at different levels.
Validate	The workflow level of data and all metadata records is changed to the Save Level when a Save button (Final, Incomplete or Pending) is selected, regardless of whether or not any changes were made to data or metadata.
DDE	The current data values and metadata are hidden until you exit each data field, at which time the value entered is compared with the current value in the database. If they differ a dialog appears asking you to select the correct value. You must tab through all data fields before the record can be saved. During save, the data record and all metadata records move to the Save Level. [Plate] > [List DDE Status on This Page] can be used to check the changes made so far and the data fields that remain to be entered on the current data record.

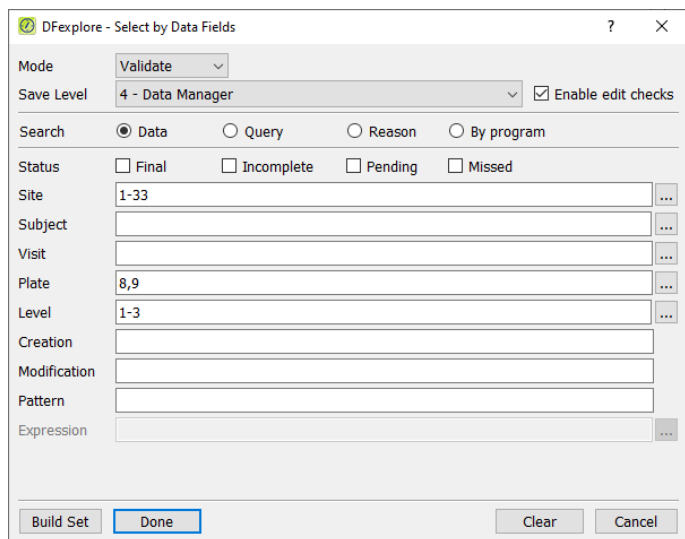
The dialog can be used to change mode, save level, and to enable or disable edit checks. It is available to users who have Data with Select permission.

The current mode and save level are shown to the left of the Save buttons at the bottom of the screen. For example, **Save m[1->2]** indicates that we are in Modify mode with a sign off level of 2, and that the data record is currently at level 1. Modes are identified by the letter **m** for Modify, **e** for Edit, **v** for Validate, and **d** for DDE.

When in View mode only the current workflow level is shown, e.g. **Save [3]**, and the message **view mode** is displayed to the right of the save buttons.

Select - By Data Fields

Ad hoc task sets can be created using the same record selection dialogs as described in [Defining Tasks](#). As with predefined task sets, the records in an ad hoc task set are also flagged with the 'T' and 't' icons. To get started, select [\[Select\] > \[By Data Fields\]](#).



To be selected a record must meet all of the specified criteria. Criteria that are left blank are irrelevant. The search criteria restrict the search to data records, query records or reason records. For example, when searching for records at level 1 you will obtain different results depending on whether you are searching for level 1 in data, query or reason records.

In this example, Plates 8 and 9 that are at workflow Level 1 with status Final are selected for all subjects at Sites 1 to 33. The selected records are to be reviewed in Validate mode with a save level of 2. Thus, whether or not a record is modified, it is raised to level 2 if it is saved using one of the Save buttons.

If you click [\[Build Set\]](#), the dialog remains open and you are able to add more records to the ad hoc task set by specifying a new set of criteria and again clicking [\[Build Set\]](#).

Click [\[Done\]](#) when you are finished building your task set and you are ready to review the records.

In addition to the record selection criteria, the dialog requires specification of the **Mode** and **Save Level**. These settings apply to both data and metadata records.

It is important to remember that modes do not grant any permission that you do not already have. Permission to view and modify data and metadata are controlled by study roles defined and assigned to users by the study management team. Thus, you are only able to select records you are allowed to see, and regardless of the mode you select, you are only able to modify data and metadata for which you have modify permission.

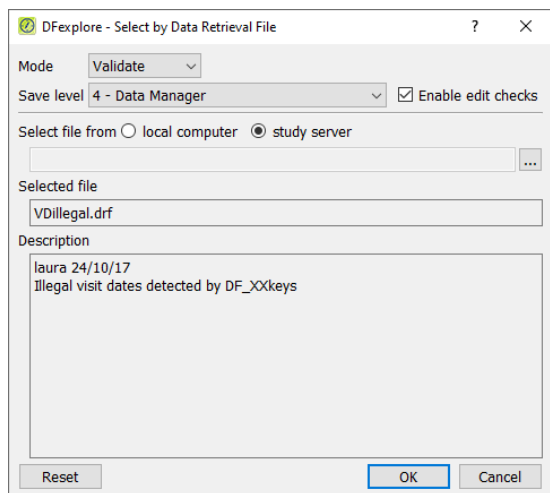
When you click **Done** a confirmation dialog indicates the number of records in the database that match the selection criteria. Click **OK** to proceed or **Cancel** to abort the selection.

If you proceed, the record list is reduced to show only those sites, subjects and visits that contain records in the ad hoc task set, and each of these records is flagged with the task icon. Just as with predefined tasks, the not completed task icon (plus symbol) changes to the completed task icon (checkmark) when a task record is saved. This shows that the record has been reviewed but does not necessarily mean that the task has been completed as intended. If the record still meets the selection criteria for the task it will come up again the next time the task is performed. All other sites, subjects, visits and records are hidden.

To toggle the current subject between task records and all records, click **Show All Records for This Subject** at the bottom of the task records list. The entire record list containing all sites and subjects can also be toggled using the menu items **Show > All Records** and **Show > Task Records**.

Select - By Data Retrieval File

This option can be used to retrieve data records listed in a Data Retrieval File (DRF). These files all have a .drf extension. They can be loaded from either the study drf folder or your local computer. DRFs can be created by running some legacy **DFdiscover** reports, by saving a current task set using **File > Save Data Retrieval File**, and by using DFmkdrf.jnl, DFmkdrf.ec, or a custom program as described in [Task Definition by Program](#). To retrieve records listed in a DRF, select **Select > By Data Retrieval File**.



The DRF in this example is named VDIllegal.drf. This is a standard **DFdiscover** DRF which lists illegal visit dates detected by **DFdiscover** report **DF_XXkeys**.

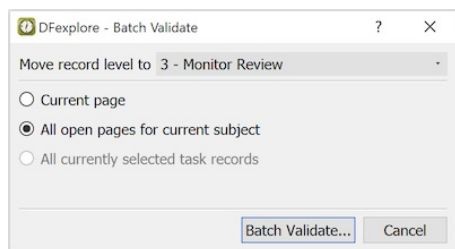
Validate mode is specified which means that the workflow level of existing data and metadata records are changed to 2. The file is selected from the study server, as this is a standard DRF. If the DRF contains a descriptive header it is displayed in this dialog when the file is selected. If each record in the DRF includes a description (e.g. explaining why it was included) it is displayed in **DFexplore**'s message window when a record is selected in the record list. The message is optional and may not be present in all cases.

Select - Batch Validate

The Batch Validate feature is used to move all matching data records to a specified workflow level in one step. You require permission for Data with Select to use this feature. Data records may only be batch validated if they meet all of the following criteria:

- You are able to retrieve the records. Records that you do not have permission to get, or which are currently locked by another user, cannot be batch validated.
- Record status is final, incomplete, pending or missed. New records cannot be batch validated.
- The records are currently at levels for which you have modify permission.
- You can only move records to levels for which you have write permission.

There are 3 batch validate selection options: move the current page only, move all open pages for the current subject, and move all records in the current task set.



In this example all open pages for the current subject are moved to workflow level 3 when **Batch Validate...** is clicked. The open pages could include visits opened by selecting them in the record list (using **Subject > Expand All Visits**) or as the result of a predefined or ad hoc task.

After clicking **Batch Validate...**, a confirmation dialog requesting your username and password is presented. This batch action requires your username and password for the first use, and for subsequent uses your password only. If you are logged in with your Microsoft account, click **Sign with Microsoft** to confirm this action. The specified records are moved immediately. No edit checks are triggered.

Using Lookup Tables

Some tasks require selecting an item from a predefined lookup table. This functionality is implemented in **DFExplore** using an edit check to achieve the desired behavior. For example, the edit check might be programmed to provide the lookup table to only specified users, users with specified roles, or users performing a specified task; and the lookup table might always appear on entry to some data field or only when an exact match can not be found automatically.

Regardless of how the edit check is programmed, if a lookup table appears while performing data entry, you are able to search the lookup table and select one of its entries (rows), or click **Cancel** to select none of them.

This example shows a lookup table which has been created for MedDRA coding. The division of each row into fields, the field labels, the order in which they appear, which fields are shown in the dialog, and which fields are returned to the edit check when a row is selected, are all customizable by the edit check programmer.

DFExplore - DFlookup: MedDRA

Search terms: FATIGUE

entries with: ANY ALL ONLY search terms in the following fields

Lookup Fields	Current Selection
<input checked="" type="checkbox"/> Lower Level Term	Chronic fatigue
<input checked="" type="checkbox"/> Preferred Term	Fatigue
<input type="checkbox"/> High Level Term	Asthenic conditions
<input type="checkbox"/> High Level Group Term	General system disorders NEC
<input type="checkbox"/> System Organ Class	General disorders and administration site conditions
<input type="checkbox"/> Lower Level Code	10066564
<input type="checkbox"/> Version	20.1

Find Previous Filter Reset

LLT	PT	HLT	HLGT	SOC	LLT CODE	VERSI
Chronic epistaxis	Epistaxis	Nasal disorders NEC	Upper respiratory tract disorders (...)	Respiratory, thoracic and ...	10066563	20.1
Chronic fatigue	Fatigue	Asthenic conditions	General system disorders NEC	General disorders and adm...	10066564	20.1
Chronic fever	Pyrexia	Febrile disorders	Body temperature conditions	General disorders and adm...	10066565	20.1
Chronic gastric stasis	Impaired gastric emptying	Gastrointestinal atonic and hypomotility ...	Gastrointestinal motility and defae...	Gastrointestinal disorders	10066566	20.1
Chronic heartburn	Dyspepsia	Dyspeptic signs and symptoms	Gastrointestinal signs and sympto...	Gastrointestinal disorders	10066567	20.1
Chronic abdominal pain	Abdominal pain	Gastrointestinal and abdominal pains (ex...	Gastrointestinal signs and sympto...	Gastrointestinal disorders	10066568	20.1
Chronic acidosis	Acidosis	Mixed acid-base disorders	Acid-base disorders	Metabolism and nutrition ...	10066569	20.1
Progression of adenocarcinoma	Adenocarcinoma	Neoplasms malignant site unspecified N...	Miscellaneous and site unspecified...	Neoplasms benign, malign...	10066570	20.1
Progression of Alzheimer's disease	Dementia Alzheimer's type	Alzheimer's disease (incl subtypes)	Mental impairment disorders	Nervous system disorders	10066571	20.1

OK Cancel Show All Fields

The top section of the dialog shows the field labels and the field values in the currently selected row. The bottom section is a scrolling list of all rows in the lookup table, typically with abbreviated field labels (acronyms) at the top of each column. If all fields can not be seen, click **Show All Fields** to reduce the display size of each column to fit them all within the current dialog. The size of each column can be adjusted by right-clicking the vertical line separating the field labels and dragging it left or right.

To search for one or more terms enter them in **Search Terms**, check the option to find entries that contain ANY, ALL, or ONLY the terms, check the fields to be searched, and click **Find** or **Filter**. **Find** displays the next matching row, while **Filter** reduces the table to display all matching rows.

After reducing the rows to a filtered set you can enter new search terms and search or filter again within the current rows. Click **Reset** to display all rows in the lookup table.

When you have found the correct row either double-click it, or highlight it and click **OK**. This returns your selection to the edit check and dismisses the lookup table. What happens next depends on what the edit check is programmed to do. Typically all or some of the fields from the row you selected are entered into specified data fields on the current page, but the edit check may be programmed to do something else.

Query Management

Queries can be created, modified and deleted by edit checks with no user intervention, or manually by selecting **Add Query**, **Edit Query** or **Delete Query** from the **Field** menu. You can also directly add or modify a query in the **Metadata editor panel** or from the specific **Query** panel.

The query dialog has the following components:

- **Title:** The title at the top of the dialog shows the context needed to identify which site, subject, visit and page the query is about.
- **Field:** The field description, as entered in the study setup, identifies the data field in question.
- **Reported Value:** When a new query is created, this field shows the value currently recorded in the data window, but you can change this. For example, if a date is unclear you might enter a best guess in the data window but change the query to indicate that the year was unclear (e.g. Jan ??,2017).
- **Category:** The category type can be one of the following default categories: missing, illegal, inconsistent, illegible, fax noise, and other. It may also be any user-defined category. For studies where multiple queries per field are allowed, the category cannot be edited after the query is created. When multiple queries are allowed on a single field, at most one query of each category is permitted per field. Based on your role permissions, you may be restricted from manually adding, changing, or deleting queries with specific categories.
- **Use:** Use can be external, meaning the query is directed to the clinical site; or internal, indicating it is for the data management site only.
- **Status:** The status of each query is updated as appropriate to one of the following:
 - **New:** The query addresses a new question which has not yet been transmitted to the clinical site.
 - **Revised:** The query addresses a revised question which has not yet been transmitted to the clinical site.
 - **Outstanding:** The query has been transmitted to the clinical site but has not yet been resolved.
 - **Pending:** The site has responded to the query but the reply has not yet been reviewed by the data management site.
 - **Resolved NA:** The query has been resolved - the requested data or correction is Not Available.
 - **Resolved irrelevant:** The query has been resolved - the query was deemed to have been unnecessary.
 - **Resolved corrected:** The query has been resolved - the requested correction or information has been received.
- **Type:** Type is Correction if the query asks for some data correction, or Clarification if the query requests additional information.
- **Detail:** A description of the issue and the requested resolution can be entered manually or, if standard queries have been predefined, they can be selected by typing a short acronym or using [...] to select the query from a lookup table.
- **Note:** An internal note, used only by data management staff, can be entered for any internal purpose, such as recording special circumstances explaining why or how a query was resolved.
- **Timestamps:** The creation timestamp is updated when a query is saved with status New. The modification timestamp is generated when a query is saved after modification of any of the fields described above. The resolution time stamp is updated when Status is changed to one of the 3 resolution types.

Clicking OK saves the query locally. It is applied to the study database when the data record is saved.

Automatic Resolution of Data Queries

Some data queries resolve automatically when the data field is corrected while others do not. For auto resolution to occur all of the following conditions must be met.

- **Query Use** = 'External'
- **Query Type** = 'Correction'

- **Query Category** = 'Missing' or 'Illegal'
- The data field does not have a Reason with status 'Rejected'

If all of the above criteria are met then:

1. if the study setup includes a legal value specification for the data field, then entry of one of the specified legal values resolves the query
2. if legal values have not been specified for the data field, then entry of any value resolves a query with category 'Missing' but not a query with category 'Illegal'.

In addition to the above auto resolution rules, edit check programmers can resolve queries when certain conditions are met using the edit check function dfeditqc. In this case there are no restrictions on the type of queries that can be resolved, other than those imposed by the edit check programmer.

Review/Approve Queries and Reasons

Central office review and approval of reasons and query replies can be performed using **Field** > **Review Queries and Reasons** or **Field** > **Approve Queries and Reasons**.

The dialog looks the same for these two options, but they differ in behavior. The **Review** dialog lists all queries and reasons on the current page, while the **Approve** dialog lists only those queries and reasons with status 'Pending'. When a query or reason is changed from status pending to approved or rejected, it is removed from the **Approve** dialog but remains visible in the **Review** dialog.

Field	Reason	Category	Status
Systolic Blood Pressure Result 1	1:Approved	Illegal	1: External - Resolved corrected
SDV Check	1:Approved		

Query

Reported Value: 181

Category: Illegal Use External Type Correction

Detail: The value entered (181) is outside of the expected Legal Range (70-180). Please review.

Note:

demo_user1 5/7/2018 13:41:24

Reply:

Status: Resolved corrected

m 1 → 1 demo_user1 5/7/2018 13:41:24

Reason

Blood pressure reading was entered incorrectly on the form. This has been corrected.


demo_user1 5/7/2018 13:41:24

Status: Approved

m 1 → 1 demo_user1 5/7/2018 13:42:39

Buttons: Previous, Next, Save, Revert, Done

To use this feature, begin by retrieving the records to be reviewed, and if necessary set the working mode and level per study workflow SOPs. Using these dialogs in 'Validate' mode is generally the best choice as it allows you to save the data records and also move them to the same level. Select the Review or Approve dialog and position it beside the data window. As you traverse the data records, all relevant queries and reasons on the current record appear in the dialog. As you select each query and reason in the dialog the relevant data field is highlighted in the data window making it easy to see the relevant item.

The Review/Approve dialogs are generally used to review and approve new reasons and query replies, but as needed you can also modify or even delete queries and reasons if your permissions allow. Note: There is one limitation. Changes cannot be made to queries and reasons on Pending, level 0 data records as this status indicates that the most recent user was interrupted during the entry of a new record and intends to complete it before it is reviewed by study managers. The two buttons below **Query Status** and **Reason Status** (each has this appearance ) can be used to save your changes to the current query or reason before moving on to the next one, or you can delay saving changes until all queries and reasons on the current data record have been reviewed, in which case an asterisk appears beside each query and reason with unsaved changes. Click **Save** to save both the reason and query on the current field. Click **Done** to dismiss the dialog without saving any changes.

If you change the status of a query in these dialogs to 'New' or 'Revised', or you 'Reject' a pending reason, the data field turns blue, and when the query and reason changes are saved the status of the data record changes to 'Incomplete' (if needed) to signify that it contains one or more outstanding problems. On the other hand, approving all of the query and reason replies on a data record does not automatically make it 'Final' but does enable the 'Final' save button, which can be selected if you want to change the data record to status 'Final'.

The Review/Approve dialog allows you to perform workflow management on the metadata independently of the data records. When you have completed your review of the metadata on one page, you can proceed to the next page in the task set. You do not need to save the data record itself, unless you have made changes to data fields that you want to keep or you want to change the data record status and/or level. The workflow level is changed on data and metadata records that you save.

Transmitting Scanned CRFs

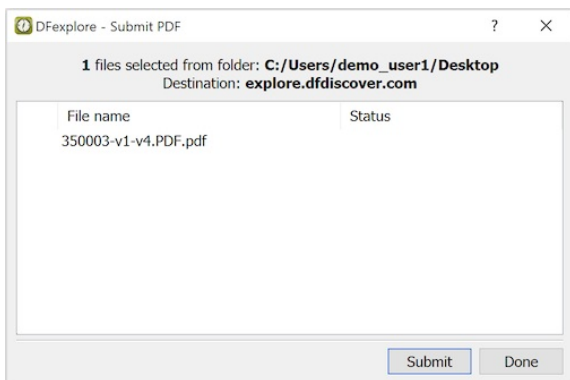
As an alternative to EDC, paper CRFs can be scanned to a PDF file, and then transmitted to a **DFdiscover** server. This capability is available via the standalone **DFsend** application and also within **DFExplore** using **File** > **Submit PDF**.

When the server receives the PDF it is processed by the system as an incoming image of a paper CRF; the pages are reviewed and entered by a user with permission to use Image View, and the pages are inserted into the database and appear in the subject binder.

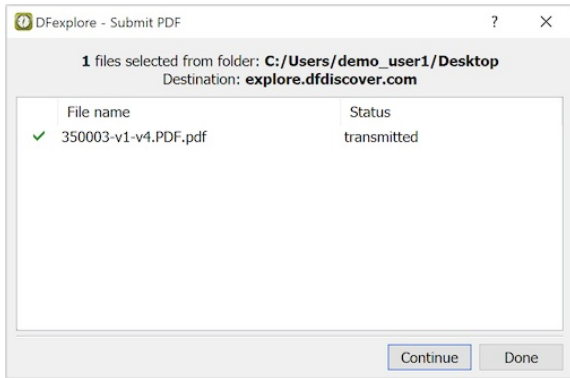
1. CRFs can be scanned in black & white, grayscale, or color and saved as a PDF file. There is a limit of 999 pages that can be included in one PDF document.
2. Start **DFexplore** and login to the destination **DFdiscover** server. Since scanned paper CRFs must include a barcode indicating the study the CRF belongs to, it doesn't matter which study you are using when you transmit a PDF. The PDF can even contain CRF pages for multiple studies, as long as all pages in the PDF file are for studies that reside on that same **DFdiscover** server.

If you use different **DFdiscover** servers for different studies, make sure you select, and login to, the correct server. Transmitting a PDF to the wrong **DFdiscover** server would be the same as sending a message to the wrong email address.

3. Select **File** > **Submit PDF** in Data View.
4. This displays the operating system file selection dialog. Use it to select the PDF file(s) to transmit.
5. The confirmation dialog identifies the **DFdiscover** server and each PDF file you selected for transmission. After confirming that these are correct, click **Submit** to start the transmission.



6. A progress bar is updated while each PDF transmission is underway. Pressing **Cancel** cancels transmission of any remaining PDFs but does not stop the current transmission.
7. When the transmissions are complete, the dialog shows the status of each PDF: 'transmitted', 'failed' or 'canceled'. Click **Continue** to select additional PDFs for transmission. **Done** dismisses the dialog.



PDFs transmitted to the server from **DFexplore** are registered in the **DFdiscover** document log. Each transmitted file is also added to the **DFdiscover** document archive.

Select **Plate** > **Context** to view the date and time the page was centrally received along with the submission method and user.



Limitations in Submit PDF

To use this feature your study role must include permission for '**DFexplore**: Data-Submit PDF'.

This feature is blocked if a study has been 'disabled' or put into 'read-only' mode by a study administrator. If a study is in 'restricted' mode, PDFs can be submitted by study and **DFdiscover** administrators only.

Importing Subject CRFs

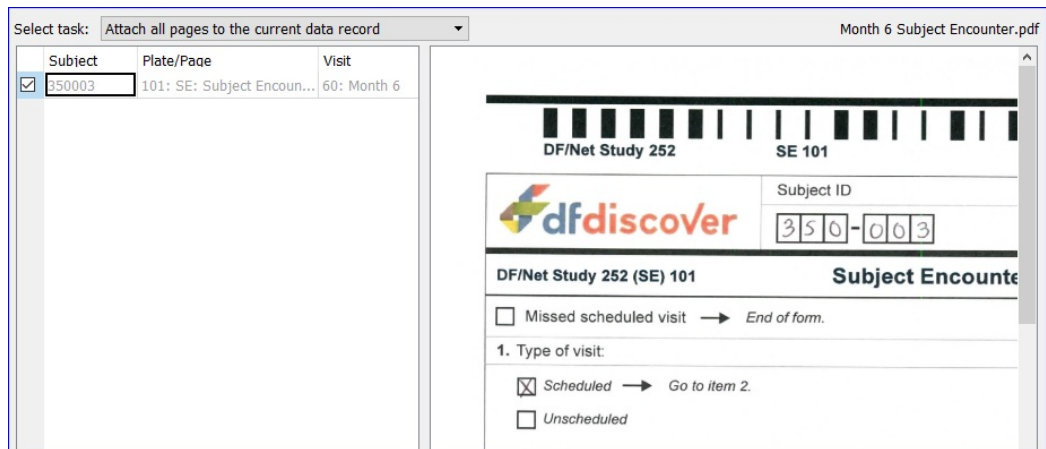
[Transmitting Scanned CRFs](#) sends one or more PDFs to the **DFdiscover** server for processing in Image View. It is yet another method for adding new CRFs to a study for data entry.

In some cases however, CRFs are not meant for separate data entry. Instead these CRFs may belong to already existing data records. This functionality is available via **Subject** > **Import Subject CRFs** for users that have permission to 'Import Subject CRFs'. With this feature, a PDF file is imported and each page can be immediately attached to an appropriate data record.

The imported pages may be supporting documentation e.g. letters, reports, test certificates, etc. or copies of paper CRFs or worksheets containing subject data.

Select **Subject** > **Import Subject CRFs** in Data View. From the file selection dialog, select a PDF for import.

The import dialog contains two main sections: a window for reviewing the PDF pages on the right, and a spreadsheet for identifying the data records they belong to on the left.



This feature has 3 modes of operation, chosen from the **Select task** drop-down:

- Attach all pages to the current data record** To use this option, the destination data record must be opened before **Import Subject CRFs** is selected. When the import dialog opens the keys identifying the current data record are displayed in the spreadsheet and cannot be changed. Simply select the check box beside each page you want to import, or click **Select All** to select all pages. Click **Import**. A dialog appears asking you to re-enter your password (you can still **Cancel**) at this point). If you proceed and enter your password (or authenticate with your Microsoft account after clicking **Sign with Microsoft**), the selected pages are imported. A results dialog appears, displaying a summary of the transaction including a list of the pages that were imported. If the current data record had one or more images before import, all imported pages become secondary images, otherwise the first imported page becomes the primary image and the rest become secondary. The imported images can be reviewed and the primary/secondary classification can be changed using the **Review Images** dialog, which is selected by clicking the image count button at the bottom of the screen or by selecting **Plate** > **Review Images**.
- Attach each page to the data record identified below:** Use this option if the PDF contains pages that belong to a number of different data records.

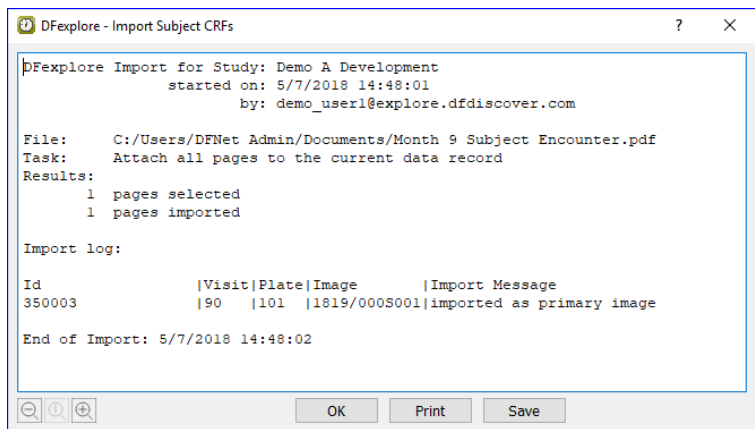
To use this option you must be able to identify the data record that is to receive each page by entering its keys (Subject, Plate/Page and Visit) in the spreadsheet. If any of the imported pages are barcoded to identify where they belong in the subject binders, values for Plate/Page and Visit are read from the barcodes; otherwise enter the appropriate numeric value in the spreadsheet, or right-click a cell to use the selection dialog. Enter the Plate/Page number first. The Visit selection list then shows only those values that are consistent with that plate, per the study visit map.

To prevent errors **DFExplore** does not allow pages to be imported if they are barcoded with a different study number. Also, users can only import pages for data records that their study permissions allow them to modify.

If a key field contains a value that is illegal or not permitted, the cell appears purple and the page selection check box is not available until the problem keys are corrected. If a page contains a barcode for a different study or the identified record is at a workflow level you cannot modify, a red X replaces the page selection check box indicating that the page cannot be imported.

After entering valid keys a check box appears which when checked indicates that the subject binder can be locked and that the page has been selected for import. If the page cannot be imported because the subject binder is locked by another user a lock icon replaces the check box and the message **This record is currently locked by another user** is displayed.

When the pages you want to import have been identified and checked click **Import** and enter your password (or click **Sign with Microsoft** if logged in with your Microsoft account). Each page is attached to the specified data record as a primary or secondary image, as described for the previous option. The assignment is displayed in the results dialog.



If a page is imported for a data record that does not currently exist in the study database, a pending data record is created and added to the subject binder.

3. **Import data entry worksheets/CRFs identified below:** Use this option if you want to import worksheets or CRFs on which data has been recorded and then use **DFdiscover's** split-screen data/image feature to enter the data into the corresponding data records.

This option begins like the previous one: the pages to be imported are identified and selected, the import button is clicked and you are prompted to enter your password (or prompted to [Sign with Microsoft](#) if logged in with your Microsoft account), after which the selected pages are imported and the results dialog appears. It differs from the previous option as follows:

- Only one page can be imported for each data record. If the same keys are entered in the spreadsheet for a second page, the selection check box becomes unavailable for that page.
- Each imported page becomes the primary image for its data record. The previous primary image (if any) becomes secondary.
- **DFexplore** builds a task set of all imported pages, and displays the first task record when you close the results dialog. If any of the imported pages did not have a matching data record before import, a data record with pending status is created and added to the task set.
- The user performs data entry by comparing the data fields with the values recorded on the imported CRF or worksheet, and entering or correcting the data fields as needed.
- All imported pages should be processed before releasing the task set, but if this is not possible they can be saved using [File](#) > [Save Data Retrieval File](#). They can then be retrieved and completed another time using [Select](#) > [By Data Retrieval File](#).

Spreadsheet Keyboard Shortcuts

The following keyboard shortcuts may be useful in the import process:

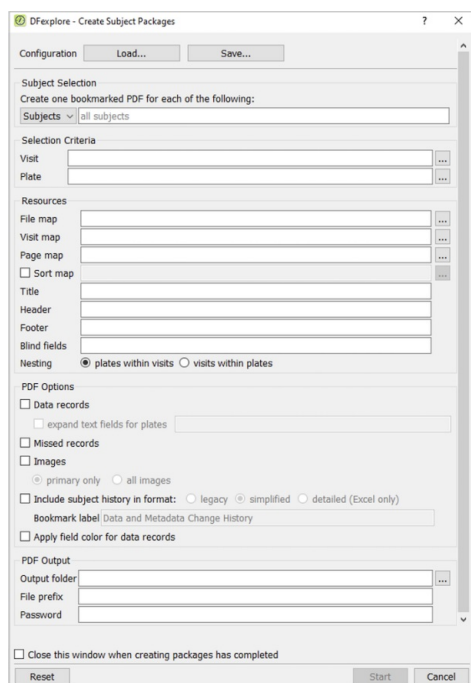
- [Tab](#) or [Right arrow](#) moves forward across the cells in each row.
- [Shift-Tab](#) or [Left arrow](#) moves backward across the cells in each row.
- Pressing [Enter](#) on a Subject cell, or completed Plate or Visit cell, moves down to the next cell in the column, as does [Down arrow](#).
- [Shift-Enter](#) on a Subject cell, or completed Plate or Visit cell, moves up to the next cell in the column, as does [Up arrow](#).
- If you know the numeric value it can be typed into an empty cell or you can over-type to change a completed cell. Plate and visit labels are displayed after the numeric value is entered in these cells.
- If you don't know the numeric value for plate or visit a selection dialog showing the legal values and corresponding labels can be launched using right-click, [Control-S](#) or by hitting Enter when the cell is empty.
- Within the selection dialogs use the Up and Down arrow keys to find the desired value and then hit Enter to select it and close the dialog.
- Plate must be entered before Visit; only visit numbers that are legal for the specified plate are displayed in the visit selection dialog.
- To enter the same value in a range of cells in any column, first select the cells (click the first cell then shift-click the last cell) and then enter the value by typing or using the selection dialog.
- To copy and paste the values from one range of cells to another, first select the cells as described above, then use [Control-C](#) (or right-click-Copy) to copy the values, then click the first cell in the destination range; finally, use [Control-V](#) (or right-click-Paste) to paste the values.
- While working within a selected range of cells, the [Delete](#)
- (Backspace) key removes the current value from all of the selected cells.
- When all keys have been completed with valid values, the space bar can be used to toggle the import selection check box on and off.

Creating Subject Packages

A subject package is a user-specified selection of data records, CRF images, metadata and change history assembled into a PDF. The PDF is viewable with a PDF viewer application, such as Acrobat Reader.

DFexplore includes a feature to create one or more subject packages, for a specific subject ID, set of IDs, or entire sites.

To start the creation of subject packages, select [File](#) > [Create Subject Packages](#). The **Create Subject Packages** dialog is displayed.



The dialog has several configuration sections:

- **Subject Selection:** Which subjects, or sites, are included? For each included subject, a unique PDF is created.
- **Selection Criteria:** Are only certain visits or plates to be included? By default, all visits and plates appearing in the database for the selected subjects are included. This can be useful for example to create packages containing only the enrollment visit or adverse event CRFs.
- **Resources:** The appearance of the contents in each package is impacted by the settings in several resource files. In most cases, the already defined study resources yield the desired results. A custom title, page header and page footer, and details for fields to be blinded in the output are also specified here. Details for the syntax of the **Blind fields** setting can be found in [Programmer Guide, DFpdf](#).
- **PDF Options:** In combination with the subject selection criteria, these options determine which data from each subject binder to include in the output. Typical settings include **Data records** and **Images**. To ensure all text fields and dropdown labels are fully displayed in the PDF, enable the **expand text fields** option. Missed records and secondary images can also be included. Change history may be included in one of three formats: legacy (*DF_ATmods* output included in each PDF), simplified (basic change history included in each PDF), or detailed (full change history created as a separate Excel file per subject). Note that including change history and all images can result in PDF documents that are very large.
- **PDF Output:** One PDF document is created for each included subject. In this section specify the folder location where each of the PDFs should be created and what prefix should be used for each generated document. The subject ID is appended to the file prefix. The complete document name for each PDF is the concatenation of the values for **Output folder** and **File prefix**, which is then followed by the current subject ID. A fixed extension of .pdf is added to complete the document name.

Complete all of the relevant settings in the dialog. Depending upon the number of subjects or sites selected, and the volume of data, the package creation step can be quite lengthy. Review that all of the settings are correct and as intended. Click **[Start]**. Review the settings summary in the confirmation dialog. Click **[Start]**.

While the package creation process is running, a progress bar is displayed. At completion, a summary dialog is displayed. Review the referenced log file (if more detail is needed) by clicking **[View Log]**. Click **[Close]** to dismiss the dialog.

The resulting PDFs are available in the folder previously specified for **Output folder**. Each PDF is viewable with a PDF viewer application, such as **Acrobat Reader**. If a **Password** is specified, resulting PDFs are encrypted and stored in binary format. The recipient needs the password to open each PDF. The summary log file is also in the same folder. If it is not needed, it can be deleted.

Data View Menus

This section describes the options available from the application menubar. The specific menus displayed, and the availability of options under each menu, varies depending on user permissions and whether an action is allowed at any given time.

File Menu

The **File** menu is similar for all views (data, list, queries and reasons) and contains the following items:

- **[Reload]** - users with **DFExplore** Developer permission can use this option to:
 - reload lookup tables,
 - reload edit checks, and
 - trace edit check execution

These functions make it possible to modify edit check code, republish it and then reload the edit checks to test the modifications and trace edit check execution as you enter and exit records and fields. In order to avoid disrupting production edit checks in use by other users, we recommend using Link

Development-Production studies for testing the changes to edit checks before publishing them.

- **Submit PDF...** - functions the same as **DFsend**. A CRF with a legible barcode is sent to the image queue of its study. CRFs with illegible barcodes are sent to the Image Router.
- **Save Data Retrieval File...** - create a DRF listing the keys of all records in the current task set. This allows reloading of this same set some time later using **Select** > **By Data Retrieval File**.
- **Save As PDF...** - create a PDF file containing data and/or images from the current subject binder or task set. Use this option to: print blank CRFs, print documents and data records side by side, or include data records with the same field color coding used in **DFexplore**.

When the option '**[] bookmarked PDF**' is checked in the **Save As PDF** dialog, blank CRF books and completed CRFs including data records, missed records and all images. are bookmarked as follows:

```
Blank CRF book bookmarks:
> CRF Book (or ID ###, if print subject id)
  > visit_label
  > plate_label
  > plate_label (page 1). -- eCRF plate across pages, append (page #).
  > plate_label (page 2)

Completed CRFs bookmarks:
> ID ###
  > visit_label
  > plate_label (data).      -- regular data record
  > plate_label (data 1).   -- when eCRF plate across pages
  > plate_label (data 2)
  > primary_image.         -- append (1), (2), ... when across pages
  > secondary_image*       -- append (1), (2), ... when across pages
  > plate_label (missed)   -- missed record
  > plate_label (missed 1). -- when eCRF plate across pages
  > plate_label (missed 2)
  > plate_label (blank).   -- blank record
  > plate_label (blank 1). -- when eCRF plate across pages
  > plate_label (blank 2)
```

If a watermark exists for your login role, it appears in the PDF file created by this menu item. Blank CRFs are not watermarked.

- **Save As Bookmarked PDF...** - create a PDF file containing data and/or images from the current subject binder or task set. This option includes many of the same options as the command line program DFpdf and includes a navigation sidebar indexed by subject ID, visit and plate. Use this option to produce a PDF containing any combination of CRF images and data records with the same color coding used in **DFexplore**, to blind specified data fields (e.g. for endpoint adjudication committees), and to password protect the PDF file.

Enter field blinding specifications as follows: **plate#s:field#s;plate#s:field#s**, and use '*' for all plates and/or all fields. For example: ***:8** (blind field 8 on all plates), **1-5:8;9:22-25,33** (blind field 8 on plates 1-5 and fields 22-25 and 33 on plate 9).

When **expand text fields for plates** is checked, text fields with a store length that is larger than the display length and dropdown fields with choice labels that are longer than the field size are expanded to fit all text for the plates specified as **##~#**. An empty plate list (no **##~#** specified) expands text fields for all plates.

If a watermark exists for your login role, it appears in the PDF file created by this action.

- **Save Task Set...** - create a PDF file containing the data record keys, set creation method, set instructions, user name and date for the current task set.
- **Print...** - print blank CRF books with subject ID and visit numbers pre-printed, or pages (containing data and/or images) from the current subject binder or task set.

If a watermark exists for your login role, it appears in the printed CRFs created by this action.

- **Print Task Set...** - print the data record keys, set creation method, set instructions, user name and date for the current task set.
- **Create Subject Packages...** - create bookmarked PDF documents containing EDC data records, images or other attached documents, and audit records for study subjects; one file per subject.
- **CDISC ODM Export...** - create ODM compliant XML files containing study data.
- **Preferences...** - set user preferences. Changes are applied immediately and persist across login sessions.
- **User Profile...** - change your contact information and/or login password.
- **New Study...** - display the login/study selection dialog so that an additional login session can be started. The current study login session is not impacted.

This can be useful if you want to compare data in 2 different studies, compare information presented in different views (e.g. list and data views) within the same study, or compare behavior for 2 login sessions with different study roles during study setup.

- **Close Study** - close the connection to the current study and return to the study selection window, where a different study or different server may be selected.

When a field in the data entry window has the focus the following **Edit** menu items are available:

- **Undo** - undo the last edit operation performed.
- **Redo** - redo the last edit operation performed.
- **Cut** - copy the contents of the current field to the system clipboard, then clear the field.
- **Copy** - copy the contents of the current field to the system clipboard.
- **Paste** - copy data from the system clipboard to the current field at the current cursor location.
- **Clear** - remove all data from the current field.
- **Select All** - select all data in the current field.

Select Menu

The **Select** menu is used to select subjects and data records for review. Selected subjects and records are tagged in the record list panel with the letter t (for task).

- **All Records...** - cancel the current selection criteria and return to the default display showing all subject binders and records.
- **By Task...** - select data records using a predefined task.
- **By Data Fields...** - select data records by: site, subject, visit, plate, level, status, etc. as well as by metadata (queries and reasons). This option requires permission for Data - with Select.
- **By Data Retrieval File...** - select data records using a previously defined data retrieval file.
- **Define Tasks...** - define individual tasks or tasks for other users.
- **Export Tasks to Local File...** - export previously defined data tasks to a local file.
- **Import Tasks from Local File...** - import data tasks from a local file.
- **Change Mode & Level...** - **DFExplore** supports 4 working modes and allows records to be moved to specified workflow levels. The supported modes include:
 - **View** - users review subject data but can not make any changes.
 - **Edit** - changes can be made (as permitted by user permissions) but the workflow level of all data and metadata remains unchanged.
 - **Modify** - the workflow level is changed to the specified sign off level, but only for those data and metadata records that are modified.
 - **Validate** - the workflow level of data and metadata records is changed to the specified save level when you select one of the Save buttons, regardless of whether or not any changes were made to data or metadata.
- **Batch Validate...** - change the workflow level of a set of records.
- **Batch Sign** - e-sign all records for the current subject or a set of selected records eligible for signing and move to a specified workflow level.

Show Menu

The **Show** menu determines which subjects and data records are listed in the study binder window. The menu items act as filters. The following choices are available:

- **All Records** - show all data records, independent of whether they are included in the current task set.
- **Task Records** - show only data records that have been assembled in a predefined or ad hoc task using the Select menu options.
- **All Subjects** - show all subject binders.
- **Potential Subjects** - show only empty subject binders (for which no data has been entered).
- **Enrolled Subjects** - show only subject binders that contain data.
- **Complete to Date Subjects** - show only subject binders with complete data for all visits completed to date.
- **Incomplete to Date Subjects** - show only subject binders containing pages marked Incomplete or Pending.

Subject Menu

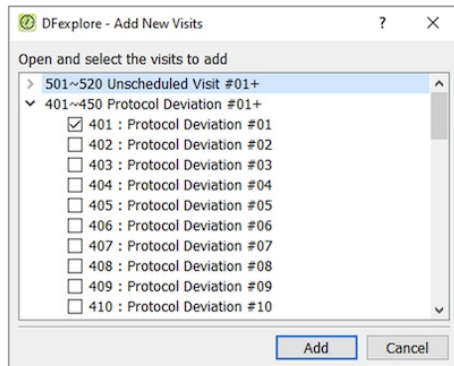
The **Subject** menu includes the following options:

- **New Subject...** - add a new subject binder to the current site for a specified subject ID. Only subject IDs which have been predefined as belonging to the current site, are accepted.
- **Expand All Visits** - open all visits in the current subject binder.
- **Collapse All Visits** - close all visits in the current subject binder.
- **Import Subject CRFs...** - import PDF documents containing CRF pages directly from the local computer.

Visit Menu

When a visit is selected in a subject binder, the following options are available:

- **Add New Visits...** - add visits which do not already appear in the subject binder. This is only available for specific visits as defined by the study coordinating center. Select the visit(s) to be added and click **Add** to add the visit to the subject binder.



- **Set Visit Missed...** - if an entire subject visit is unavailable (e.g. because the subject missed the visit) this option can be used to mark it missed.

If a missed visit report page has not been created for the study a default dialog appears. In this dialog, choose a reason from the choice list. Additional text can be entered to explain why the visit has not been completed. All required pages in the visit are then marked 'Missed', data entry is blocked on all of these pages, and the reason is displayed in the reason window whenever one of these pages is selected.

If an overdue visit query exists it is removed when the visit is marked missed.

- **Unset Visit Missed...** - undo the previous option if the default dialog was used. If a special missed visit report page has been completed it remains in the study database, just like any other study record, unless it is deleted.

Plate Menu

The **Plate** menu provides the following options for the current page:

- **Save** - offer the same 3 options provided by the save buttons at the bottom of the window: Final, Incomplete and Pending.
- **Revert to Last Save...** - undo all unsaved changes that have been made to the current page.
- **Review Images...** - display all images (primary plus all secondaries) and allow user to: select which image to call primary, delete secondary images, and correct keys on secondary images.
- **Change Keys...** - correct any errors in the key fields that might have occurred when a page was saved, including corrections to the study number, subject ID, visit number and plate number.
- **Delete This Page...** - delete a data record. All of the data, queries, reasons and images associated with the record are deleted from the database. Deleting a record is a drastic, and unusual measure. Confirmation is required, and a reason must be entered to explain why the record is being deleted. Once a reason for deletion is applied, you are required to enter your password to confirm and complete the delete process. If logged in with Microsoft, click **Sign with Microsoft** to authenticate with your Microsoft account to complete the delete process. The delete action, the reason and your user name appear in the audit trail report created by **DF_ATmods**. Permission to use this option is typically tightly controlled.
- **Set Page Missed...** - if a page is unavailable, and may never be available, this option can be used to mark it missed. Choose one of the standard reasons, or 'other'; additional details explaining why the page was missed can be entered in this dialog.

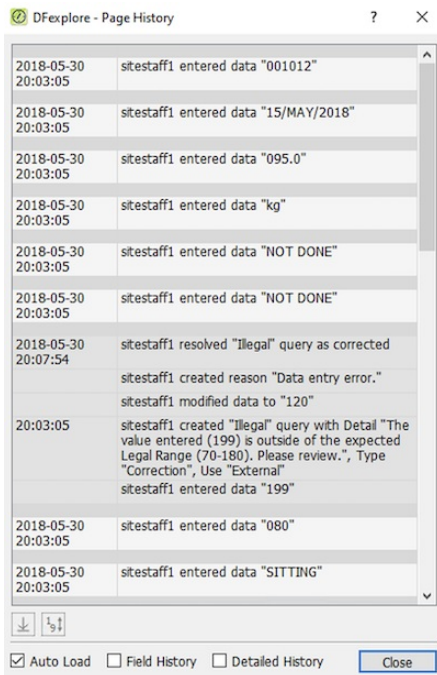
A page that is marked missed cannot contain data. Thus pages that have already been saved cannot be marked missed unless the data record is first deleted. Also if data has been entered into data fields on a new record before it is marked missed, the data fields are cleared when marking it 'Missed' is confirmed. After a page is marked missed all data fields become inactive to prevent data entry.

If a missing page query exists it is removed when the page is marked missed.

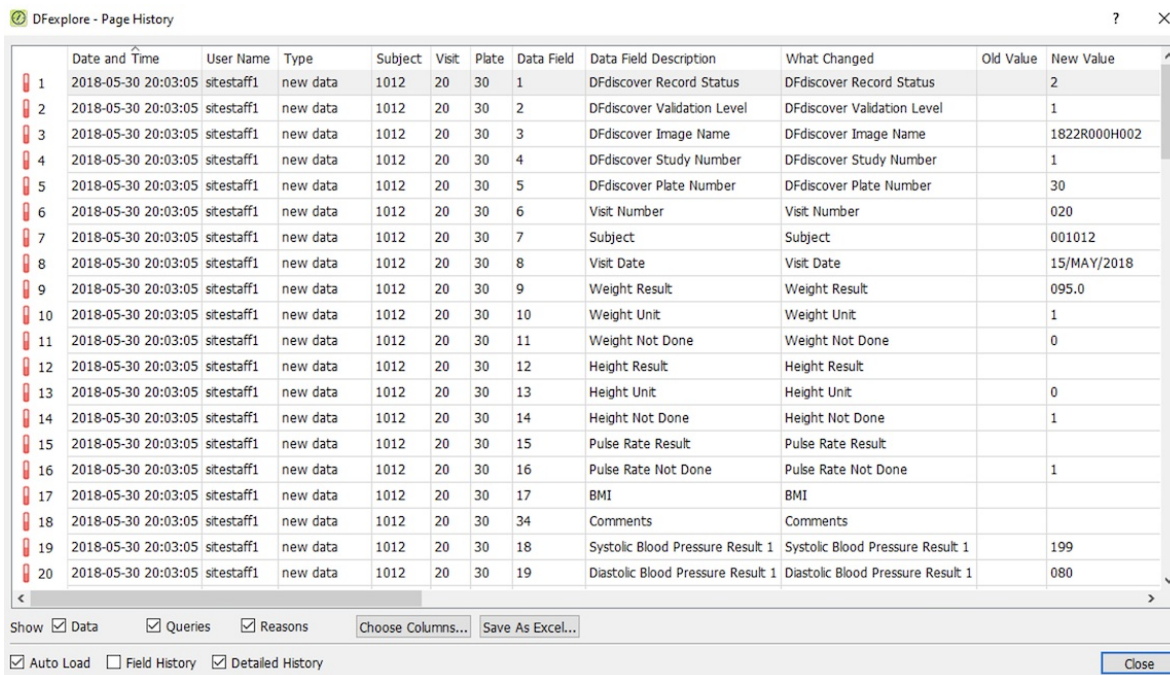
Study managers may add a query to the subject ID of missed records to request additional information from the clinical site.

- **Unset Page Missed...** - this undoes the previous option, removes any data query that might have been added to the subject ID field, and enables data entry.
- **Context** - display the date and time the page arrived (if one exists), and the source of the page.
- **Show Field Properties** - display key properties of all fields defined on the current page, including: name, description, style, need, type, format and legal values.
- **List All Outstanding Problems on This Page** - lists each field with a problem on the current page including: required fields that are blank, illegal values, outstanding queries and rejected reasons.
- **List History of All Changes on This Page** report all changes made to data fields on the current page. The page history window is non-blocking and can be left visible if needed. There are two output options - simple and detailed. The simple page history is grouped by field.

Auto load reloads the page history for the selected page currently displayed in data view. Selecting a field in data view highlights the field in the history window. Check the **Field History** option to filter the history of changes to the selected field only.



The detailed output is a tabular listing. The listing can be filtered to include/exclude rows showing changes made to data, queries or reasons. The columns included in the listing can be adjusted by clicking [Choose Columns...](#) and including/excluding columns. The output can be saved to Excel.







Further options for viewing the history of changes are available via the **DF_SBhistory** (History of Changes) report, the **DF_ATmods** legacy report, and the -history option of the **DFexport** command.

- [List DDE Status on This Page](#) - during Double Data Entry, lists the fields that have not yet been entered, and the fields that have been changed from their previous value.
- [Attach Subject Document...](#) - displays a file selection dialog to select PDF, DICOM (dcm, dic, dicom), image (png, jpg, jpeg, bmp), and AV (mp3,wav,avi,mp4) file types, and attach the selected file to the current record as a supporting document. Documents can be reviewed later with the review images dialog. Attached files can each be up to 25MB in size.

Field Menu

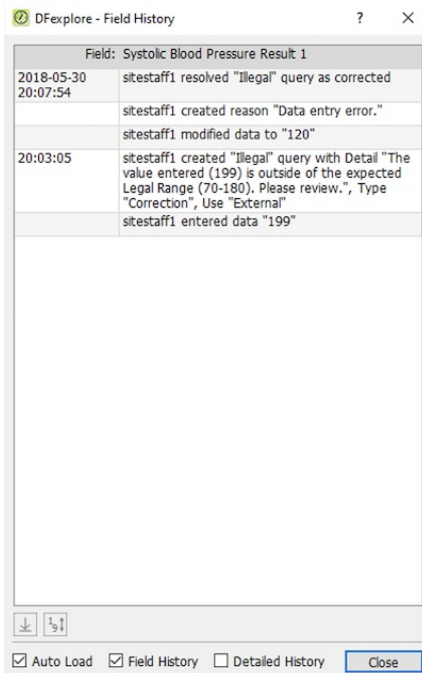
The **Field** menu provides field-level functions. Access to these functions depends upon the state of the current field and the permissions you have been granted by the study sponsor. The functions include:

- [Set Field Missing](#) - assign a predefined missing value code to the current field, or remove the missing value code previously assigned. Missing values may also be accessed using the metadata panel. After applying a missing value code, the keyboard shortcut **[Control] + [M]** can be used to apply the same missing value code to other data fields.

- **Revert to Last Save...** - return the current data field to the state it was in when the page was opened; this includes the data value itself as well as the presence/values of any field metadata.
- **Add Reason for Data Value...** - explain the current data value with a new reason. The reason dialog can also be accessed through the metadata panel. If there are outstanding (not yet resolved) queries on the data value, which were previously defined with the auto-resolve attribute enabled, adding a reason to the data value also resolves each such query.
- **Edit Reason for Data Value...** - update the reason of the current data value. The reason dialog can also be accessed through the metadata panel.
- **Delete Reason for Data Value...** - delete the reason on the current data field (note: permission to use this option is typically tightly controlled).
- **Reply to Query...** - reply to an unresolved query on the current field. The reply dialog can also be accessed through the metadata panel. Some queries can be resolved by correcting the data field and do not require a direct reply. If the study coordinating site wants a direct reply to the query, the phrase **(reply required)** appears at the top of the Query metadata window. Can also be performed by clicking .
- **Add Query...** - add a new query to the current data field. This function is also available via the metadata panel. Can also be performed by clicking .
- **Edit Query...** - modify a query on the current data field. If more than one query is present on the field, use the arrows in the Query window to select the correct query for editing. Can also be performed by clicking .
- **Delete Query...** - delete a query from the current data field. If more than one query is present on the field, use the arrows in the Query window to select the correct query for deletion. Can also be performed by clicking .
- **Approve Queries and Reasons...** - approve or reject pending reasons and query replies, on the current page.
- **Review Queries and Reasons...** - review all reasons and queries (resolved and unresolved) on the current page.
- **Show Field Properties** - list all data definition properties of the current data field, including: name, description, style, need, type, format, legal values, edit checks, etc.
- **List History of All Changes on This Field** - report all changes made to the current data field.

There are two output formats - simple and detailed.

Auto load reloads the field history for the current field selected in data view. Uncheck the **Field History** option to view the history of all changes on the current page.



The detailed is a tabular listing. The listing can be filtered to include/exclude rows showing changes made to data, queries or reasons. The columns included in the listing can be adjusted by clicking **Choose Columns...** and including/excluding columns. The output can be saved to Excel.

	Date and Time	User Name	Type	Subject	Visit	Plate	Data Field	Data Field Description	What Changed	Old Value	New Value
1	2018-05-30 20:03:05	sitestaff1	new data	1012	20	30	18	Systolic Blood Pressure Result 1	Systolic Blood Pressure Result 1		199
2	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Status		1
3	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Level		1
4	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Image Name		0000/0000000
5	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Study Number		1
6	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Plate Number		30
7	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Visit Number		20
8	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Subject ID		1012
9	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Site ID		1
10	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Report Number		000000
11	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Page Number		0
12	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Reply to Query		
13	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Field Description		Systolic Blood Pressur
14	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Reported Value		199
15	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Category Code		2
16	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Refax Code		2
17	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Detail		The value entered (1
18	2018-05-30 20:03:05	sitestaff1	new query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Note		
19	2018-05-30 20:07:54	sitestaff1	change data	1012	20	30	18	Systolic Blood Pressure Result 1	Systolic Blood Pressure Result 1	199	120
20	2018-05-30 20:07:54	sitestaff1	change query	1012	20	30	18	Systolic Blood Pressure Result 1	Query Status	1	5

Further options for viewing the history of changes are available via the **DF_SBhistory** (History of Changes) report, the **DF_ATmods** legacy report, and the -history option of the **DFexport** command.

Window Menu

Through the Reports View, it is possible to create new, undocked windows. Those windows remain visible until closed, even if you change to another view. To dock or close all of these windows, use these menu items:

- **Dock All Report Windows** - any open and undocked report windows are returned to a docked state.
- **Close All Report Windows** - any open and undocked report windows are closed.

Help Menu

The **Help** menu launches the help viewer application and displays information about **DFexplore**. It also includes additional study information:

- **Topics** - display the **DFexplore** user guide.
- **Certificate Info** - display the status of the SSL certificate provided by the server. Use this to confirm the encryption status of communication between **DFexplore** and the **DFdiscover** server.
- **Color Coding** - display a summary of the colors used and their meaning.
- **Task Instructions** - display the instructions for the current task (if any).
- **Show Roles** - list the role(s) you have been assigned in the current study.
- **Study Help** - display the study level help.
- **Plate Help** - display the plate level help for the current plate.
- **Field Help** - display the field level help message for the current field. This may be overridden by the last `dfhelp()` message generated during execution of field enter edit checks.
- **About DFexplore** - display version and copyright information. Confirm that you are running the up-to-date version required by the server. Confirm the security settings of your server connection. On macOS, this menu item appears under **DFexplore** > **About DFexplore**.



Queries View

The Queries View aids in the review and management of queries. It has features that are specific to queries.

Site / Subject	Visit : Page	Field : Category	Status & Replies
350001	Month 5 : LB: Hematology Results	Missing Page	Outstanding (New, in report not sent) Modified by: datafax 12/15/2017 13:02:59
350001	Month 5 : SADH: Study Drug Adherence	Missing Page	Outstanding (New, in report not sent) Modified by: datafax 12/15/2017 13:02:59
350001	Month 5 : AA: Acceptability Assessment	Missing Page	Outstanding (New, in report not sent) Modified by: datafax 12/15/2017 13:02:59
350001	Month 5 : RCX: Reactogenicity	Missing Page	Outstanding (New, in report not sent) Modified by: datafax 12/15/2017 13:02:59
350001	Month 6 : SE: Subject Encounter	2b. Number of pills : (Missing)	Resolved corrected Resolved by: lisa 9/24/2017 13:10:38
350002	Screening : DM: Demographics	Sex := 1 (Inconsistent) Detail: Value does not match	Pending Modified by: eric 4/25/2018 11:56:20 Replied by: demo_user1 5/14/2018 13:26:36 Reply Text: Waiting for response from site
350002	Screening : VS: Vital Signs	Missing Page	Outstanding (New, in report not sent) Modified by: datafax 12/15/2017 13:02:59
350002	Enrollment	Overdue Visit	Outstanding (New, in report not sent) Modified by: datafax 12/15/2017 13:02:59
350002	Month 1	Overdue Visit	Outstanding (New, in report not sent) Modified by: datafax 12/15/2017 13:02:59
350002	Month 2	Overdue Visit	Outstanding (New, in report not sent) Modified by: datafax 12/15/2017 13:02:59
350002	Month 3	Overdue Visit	Outstanding (New, in report not sent) Modified by: datafax 12/15/2017 13:02:59
350002	Month 4	Overdue Visit	Outstanding (New, in report not sent) Modified by: datafax 12/15/2017 13:02:59
350002	Month 5	Overdue Visit	Outstanding (New, in report not sent) Modified by: datafax 12/15/2017 13:02:59
350002	Month 6	Overdue Visit	Outstanding (New, in report not sent) Modified by: datafax 12/15/2017 13:02:59
350002	Month 7	Overdue Visit	Outstanding (New, in report not sent) Modified by: datafax 12/15/2017 13:02:59
350002	Month 8	Overdue Visit	Outstanding (New, in report not sent)

The Queries Table

Each query is identified by the subject ID, visit and page on which it occurs. Under the heading **Field : Category** the data field is identified along with its current value and the category (in brackets). If necessary, this may be followed by a description of the question from the study coordinating site. The last column shows the current status of each query, when status was set and by whom, and the current reply made to the query (if any).

Each query is marked with a symbol that shows its current status: a green filled rectangle for resolved queries, a blue partially filled rectangle for queries that are outstanding, and an orange outline rectangle for pending queries (i.e. where someone has responded to the query but the response has not yet been reviewed by the study coordinating site).

Double-clicking a query closes Query View and opens Data View with the focus on the field to which the query is attached. This makes it easy to locate the field that needs to be corrected or to enter a reply to the query or a reason explaining the data value.

When finished with the data field in Data View and having saved any changes, click [Return to Query View](#) at the bottom of the subject binder list.

Query Status

Query status has one of 3 possible values:

- **Outstanding:** the query still needs to be addressed
- **Pending:** the query has been addressed and is waiting for someone at the study coordinating site to review it
- **Resolved:** the problem has been solved. This may occur automatically, for example when a legal value is entered into a field that has a query with category 'missing' or 'illegal'. Or a query may be resolved by someone at the study coordinating site. Query resolutions are classified in one of 3 ways:
 - resolved **corrected** - always the desired solution
 - resolved **NA** - the requested data/information is not and will not be available
 - resolved **irrelevant** - another value or response has rendered this query irrelevant

Queries View Menus

The available menu actions change when Queries View is selected.

The Show Menu

The **Show** menu is used to filter the queries to be displayed in the queries table.

The following filters are available:

- [Task Queries](#) - include only queries on plates that match the defined task

- **All Queries** - include all queries
- **Outstanding Queries** - include queries that still need to be addressed
- **Resolved Queries** - include queries that have been resolved
- **Pending Queries** - include queries that are awaiting review by the study coordinating site
- **Query Category** - include queries that have the specified category code
- **Data Correction Queries** - include outstanding queries that request data corrections
- **Data Clarification Queries** - include outstanding queries that require a detailed reply
- **Outstanding Queries Modified in the Past** - include outstanding queries modified in the past 5, 10, 15, 20, 25 or 30 days
- **Outstanding Queries Modified More Than** - include outstanding queries modified more than 5, 10, 15, 20, 25 or 30 days
- **Search Queries** - display a search dialog for queries with specified properties. This provides the greatest flexibility and specificity for locating queries.

- To be selected, a query must match all of criteria and you must have permission to view the query. Criteria left empty are not considered in the search.
- To further specify subject selection criteria based on multiple criteria across multiple plates ([Selecting Subjects based on Criteria](#)), click [...].
- If **Filter** is checked, clicking **Find** reduces the query list to queries that match the search criteria, and the search dialog closes.
- Otherwise search **Direction** is applied to find the first match starting from the top of the list, or from the currently selected query and **Find** changes to **Find Next**.
- Searching for a text match in the **Detail**, **Note** and **Reply** fields is case insensitive unless **Match case** is checked.

The Query Menu

This menu has one action, **Go To Data Field**. The menu action is available after a query has been selected in the Queries table. Selecting this option changes to the Data view, opens the relevant subject binder, visit, and page, and places the focus on the field that has the query. This allows you to find, review, and respond to outstanding queries in the context within which each query was created.

A quicker way to jump to the relevant data field is to double-click the query in the Queries table.

To return to the queries table after reviewing a query in Data View, click **Return to Queries View**.

Reasons View

The Reasons View is used for review of reasons that have been added to explain unusual values, add comments or explain why a data value was changed. Reasons are analogous to comments written in the margins of a paper CRF.

Site 30 - 10 reasons (1 rejected and 3 pending)			
Site / Subject	Visit : Page	Field : Reason	Status
Site 10 - New York			
Site 20 - Austin			
Site 30 - Denver			
30001	Screening : Eligibility	Investigator Signature (Eligibility) : Set by DFws Import	Approved - laura_test 7/19/2022 18:24:55
30002	Enrollment/Vaccination #1 : Laboratory Results- Hematology	Lymphocytes Result : Confirmed, value is outside the legal range but correct as entered.	Pending - mark 12/8/2022 18:23:46
30002	Enrollment/Vaccination #1 : Laboratory Results- Chemistry	AST Result : Data entry error, now corrected.	Pending - mark 12/8/2022 18:24:48
30002	MH Log Page 01 : Medical History Log	Does subject have any medical history : test	Rejected - demo 11/5/2024 13:14:03
30002	MH Log Page 01 : Medical History Log	1. Medical History Term : clarified	Approved - demo 4/2/2024 15:43:22
30002	MH Log Page 01 : Medical History Log	MH Start Date 1 : test	Approved - demo 4/2/2024 15:35:07
30002	MH Log Page 01 : Medical History Log	MH Ongoing 1 : test	Approved - demo 4/2/2024 15:35:07

The Reasons Table

Each reason is identified by the subject ID, visit, and page on which it occurs. Under the heading **Field : Reason**, the data field is identified, followed by the reason that was entered to explain the current value. The last column shows the current status of each reason, when the status was set, and by whom.

Reason Status

Reason status has one of 3 possible values:

- **Pending**: the reason has not yet been reviewed by the study coordinating site
- **Approved**: the reason has been reviewed and accepted by the study coordinating site
- **Rejected**: the reason has been reviewed but has not been accepted by the study coordinating site. For example, some data fields may be essential to a study and only accepted as missing in very rare circumstances. Typically when a reason is rejected the study coordinating site will add a query to explain why the reason is inadequate

Reasons View Menus

The available menu actions change when Reasons View is selected.

The Show Menu

The **Show** menu is used to select the reasons to be displayed in the reasons table.

The following filters are available:

- **Task Reasons** - include only reasons on plates that match the defined task
- **All Reasons** - include all reasons
- **Approved Reasons** - show reasons that have been approved by the study coordinating site
- **Rejected Reasons** - include reasons that have been rejected by the study coordinating site
- **Pending Reasons** - include reasons that are awaiting review by the study coordinating site
- **Search Reasons** - display a search dialog for reasons containing specified text strings

The Reason Menu

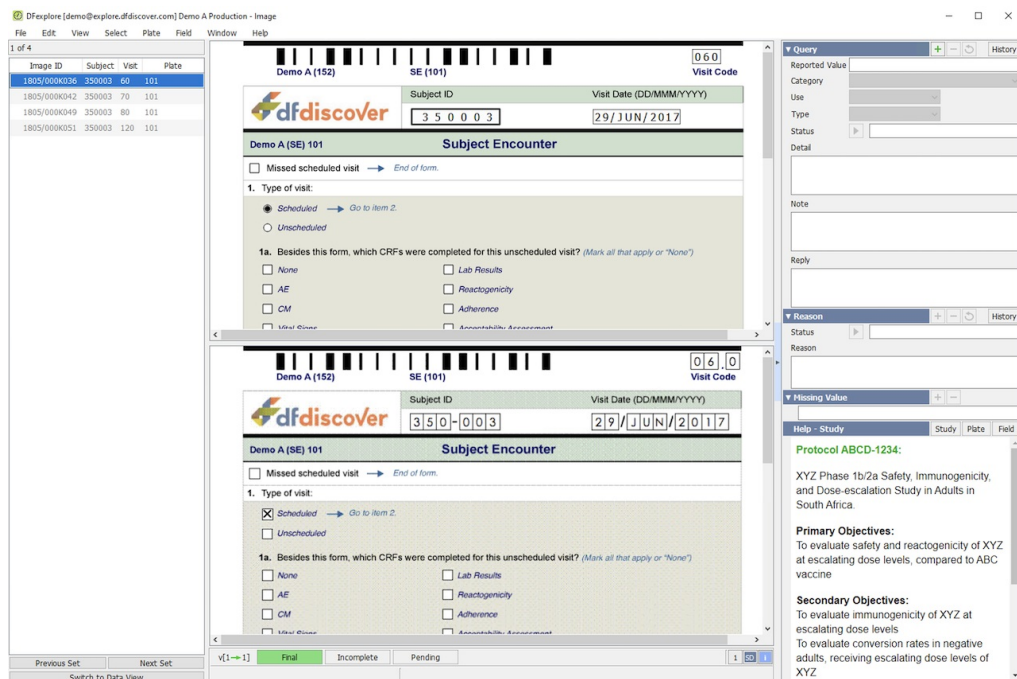
This menu has only one option, **Go To Data Field**. The menu action is available after a reason has been selected in the Reasons table. Selecting this option changes to the Data view, opens the relevant subject binder, visit, and page, and places the focus on the field that has the reason. This allows you to find and review reasons in the context within which each reason was created.

A quicker way to jump to the relevant data field is to double-click the reason in the Reasons table.

To return to the reasons table after reviewing a reason in Data view, click **Return to Reasons View**.

Image View

Image View is used to enter new data records from paper case report forms (CRFs) that have been sent to the **DFdiscover** study server, or to enter new data records from hardcopy CRF pages you have in hand and do not plan to scan into the system.



When a **DFdiscover** server receives a scanned CRF page it reads the barcode to identify the study and CRF plate, routes the page to the study, and then uses ICR (intelligent character recognition) to read the data fields and complete a first draft of a new data record. These records are stored outside the study database. They must be reviewed and saved to the study database to become available to users in Data View.

DFdiscover ICR reads check/choice boxes, numbers, dates and visual analog scales, and accuracy depends on how clearly each field has been completed. Any ICR errors must be corrected, all text fields must be manually entered, and comments written in the margins must be reviewed and perhaps entered as reasons or missing value codes.

Use **Tab** or **Return** to move forward through the data fields, and **Shift+Tab** or **Shift+Return** to move backwards. This will ensure that you traverse all field entry and field exit edit checks designed to assist data entry. When necessary the 2 screens will scroll together to show the same data fields in the data and CRF windows. You can also use **Ctrl+T** or **Ctrl+B** to scroll the CRF image screen by itself to the top or bottom respectively to check something that has scrolled by. Alternatively, if you have a large monitor the screen can be split vertically to display a full page on each side (see [User Settings](#)).

While entering new records, click **Previous Set** to move backward in the list of new records to get an earlier set, or click **Next Set** to move forward in the new record list to get the next available set. Records that have already been entered or that are currently being entered by another user will be skipped. The Next and Previous direction depend on whether you selected to sort by 'oldest to newest' or 'newest to oldest' in the record selection dialog (see below). The meaning of 'Set' also depends on what you selected in this dialog - it could be one or more documents or a specified number of records with specified visit and/or plate numbers.

If you have many CRF pages that need to be entered but not sent into **DFdiscover**, you can use Image View in EDC Data Entry mode to enter these pages or use Data View to perform the same task. The only difference is that data entry in Data View is performed within one subject binder at a time, while Image View allows you to work independent of subject binders.

New records are typically saved to the study database at workflow level 1 but it is possible to save new records directly to other levels. Image View is typically used only by data entry staff at the study coordinating site; this option is not normally made available to clinical sites.

The Record Selection Dialog

Image View supports 4 options for building a set of records to be entered. These include: **Automatic Retrieval...** and **Manual Retrieval...** for entering data from previously submitted (email, **DFsend**, fax) CRF pages, **EDC Data Entry...** for entering data from hardcopy CRF pages or other sources held outside of **DFdiscover**, and **By Task** which applies automatic record selection rules that have been predefined for a particular user or study role using **Define Image Tasks**.

Manual Retrieval facilitates the easy selection of specific records from the list of pages awaiting data entry, or searching for records with specified plate and/or visit numbers.

Image ID	Subject	Visit	Plate
1738/001K001	350004	010	101
1738/001L008		010	101
1805/000F009		010	101
1805/000K009		010	101
1805/000L009		010	101
1807/0005009		010	101
1807/0009009		010	101
1819/000P001	350003	010	101

Since visit 1-10 were specified, only these visits were listed when **Get List** was clicked.

If ICR was able to read the key fields (ID, Visit and Plate) they will appear beside each page name (yyww/ffffppp, where yy=year, ww=week, ffff=image, ppp=page). Records can be selected individually using a mouse click to select one record and Shift-click to select all records between the last selection and the Shift-click record, or all records can be selected using **Select All**.

To assemble the selected records click **OK**.

Automatic Retrieval allows users to get a specified number of documents, pages or plates at a time, and repeat this process as desired, by clicking **Get Next Set of New Records**. This avoids having to return to the record selection dialog after each set has been entered.

The current status of the new record queue is updated and displayed at the top of Record Retrieval dialog each time it is opened. In this example there are 63 CRF pages awaiting data entry of which 0 are currently locked by other users.

We recommend selecting one document at a time and processing the oldest documents first, but it is possible to select a specified number of pages, to only enter specified CRF plates, or to enter the most recent arrivals first.

EDC Data Entry is used to build a specified set of blank data entry screens for data entry from sources residing outside of **DFdiscover**.

Some or all of the keys may be specified. If subject IDs alone are specified, a complete CRF book, as defined in the study visit map (consisting of all required and optional visits and all required, optional and missed visit plates), will be created for each specified subject ID. A maximum of 999 subject IDs and 10,000 data records can be included in each EDC Data Entry set. If subject ID is not specified, you must indicate the number of cases to be created.

If data entry is interrupted, only those records that have been saved to the database will exist in the database; building a set of blank screens does not automatically put blank records into the database.

This example creates data entry records for visit 0 plates 1 and 2 for each of subjects 55034 to 55039, 12 records in total.

This example creates 100 data entry records for visit 0 plate 1. The subject IDs have not been specified and thus must be entered before each record is saved.

By Task is used to build a specified set of data entry records following a task specification. To define a new task, click **...** at the end of the **Task** input field. Select **New Task** from the list and then complete the task definition dialog. This example shows a task created by 'jack' for users with the 'Data Manager' role. Since jack owns the task only he can modify it.

You cannot save entered records in Image View for which you do not have permission. However, it is possible to select an image for which ICR failed to read the keys, and then after entering the keys discover that you cannot save the record. Also if ICR misreads the keys and you have limited permissions, you may be prevented from seeing a page that you should see in the list of received pages. These limitations argue against giving the clinical sites access to Image View, except perhaps for EDC Data Entry only.

Whether using manual or automatic record retrieval, set the **Save Level** to the workflow level at which new records are to be saved. Typically level 1 is chosen, but it is possible to save new records to any workflow level.

New data entry is always performed in Validate mode, which allows records to be saved even if no changes are made. The mode and workflow levels are shown beside the Save buttons. For example **Save v[0->1]** indicates that you are in Validate mode, and that data and metadata records will be moved from workflow level 0 to workflow level 1, when you click **Final** or **Incomplete**. New records saved with Pending status (to indicate that data entry was not completed) are saved to the study database but remain at workflow level 0.

The check box, **Enable Edit checks**, can be used to enable or disable edit checks during new data entry. Typically edit checks are enabled during new data entry but you may want to delay them to a later stage in your data management workflow process.

Entering New Records

Data entry is performed as already described for [Data View](#). The main difference is that ICR will have already completed many of the data fields and thus the task is to compare the ICR reading with what was written on the CRF page, and to correct any ICR errors and enter any text fields (which are not read by ICR).

If NA or other missing value codes have been written on the CRF, the corresponding missing value code can be selected from the Field menu or using the Missing Value widget in the bottom left corner of the screen. After applying a missing value code in either of these ways, keyboard shortcut **Control + M** (**Command + M** on macOS) can be used to apply the same missing value code to other data fields.

If explanations have been printed in the margins, they can be entered using the Reasons widget, also located in the bottom left corner of the screen.

If you need to know when a CRF page arrived or the sender identification, select **Plate** > **Context**.

Image: 1819/000T001
Page: 1 of 1
Sender: DFsend Submit PDF:demo_user1:FrameMaker file for DFsend snip.pdf
Arrival: Mon May 7 17:48:18 2018

In this example the current CRF page is page 1 of a 1 page document. The Sender may be the identification of the sending scanner or fax machine, or the username that submitted the document. The Image is a unique identifier created by **DFdiscover** for each CRF page.

Entering Resubmitted CRFs

It is not unusual for a CRF page to be corrected and resubmitted. For each new record, **DFdiscover** checks to see if the keys (ID, Plate and Visit) match an existing database record. If a match is found you will be asked if you want to load the existing data record (including reasons and queries) into the data entry window. This will allow you to compare the newly arrived CRF page with the current version of this data record in the study database. **DFdiscover** will not allow you to enter a matching record into the database without first loading the existing data record. When you save a matching record you will be updating the existing data record with any changes you make; and the new CRF image will become the primary image associated with the data record.

The old image is not deleted, and can be reviewed at any time by selecting **Plate** > **Review Images** or by clicking the image count button in the bottom-right corner of the **DFexplore** window. The **Review Images** dialog shows the date and time each image arrived and allows you to change which image is classified as the primary copy, correct keys if an image has become attached to the wrong data record, or delete images that are no longer needed.

If you process more than one image for the same data record in the same session the last image saved will become the primary image and the previous ones will become secondary. The split screen in Image View shows only the current data record + primary image. Thus returning to a secondary image in the Image View record list will display the image but not the data record. This helps to ensure that users realize they are looking at a secondary image that has been superseded by another image in the record list.

After loading the existing data record, if you discover that you have made a mistake, select **Plate** > **Revert to Initial State...** to undo all changes to the current record.

High Definition (HD) Images Setting

The new High Definition (HD) Images Setting, together with the grayscale and color image handling, is a significant new feature in **DFdiscover**, which helps modernize **DFdiscover** by displaying higher quality images.

The default setting is to display standard definition (SD) images (100 dpi) in order to reduce loading time and save cost. The central data management office can enable HD images (300 dpi) to be received for a study via **DFadmin**. Individual users can determine whether they wish to view the HD images in **DFexplore**. In other words, in **DFdiscover** 2016.0.0, users can receive and display HD images if enabled at the study level by the central office. However, if HD images are not enabled centrally or the documents are not imaged at high definition locally (e.g. if they are scanned at 100 dpi and not 300 dpi), they will not be available in **DFdiscover** to users.

To enable the HD setting in **DFexplore**, click the button at the the lower-right corner of the the screen in Image View: **SD**, which will change to: **HD**. If there is an HD version of the image available, the screen will refresh with the HD image. If HD is not enabled at the study level or an HD image was not transmitted, the SD/HD toggle will change to: **HD**. If there is no HD version of the image available, the HD setting will be enabled but the SD image will be displayed.

Like other screen settings such as previous screen location and size, the HD setting is stored locally in user's device-specific settings. This allows you to easily work over a slower laptop connection with HD mode disabled but enable HD mode on another device, an office computer perhaps, which has a fast internet connection.

Also, users are able to export HD images using **DFpdfpkg -hd**. The default behavior for **DFpdfpkg** is to export SD images only.

IMPORTANT: High Definition (HD) is only applied to documents which arrive via email attachments, **DFsend**, or **File** > **Submit PDF**, and is not applied to faxed documents.

Correcting the Keys

Each new page has 4 keys which together uniquely identify it: the **DFdiscover** study number, plate number, visit number and subject ID. The study and plate numbers are always in the barcode, the visit number can appear either in the barcode or as the first data field on the page, and the subject ID always appears as the first data field following the visit number. It is critical that these keys are correct, and they should be carefully checked before a new record is saved to the study database.

If ICR has misread a subject ID or visit number data field, they can be corrected by modifying the data field. However, to correct the keys as they appear in the barcode, you must select **Plate** > **Change Barcode** and use the **Change Barcode** dialog.

When the Plate and/or Visit number are changed the correction will appear immediately in the new record list, but if the study number is changed the page is sent to the Image Router and will be removed from the new record list of the current study.

Switching to Data View

While entering new records you can open the current subject binder to review and/or modify other records, using [Switch to Data View](#) at the bottom of the record list. Before switching to Data View you will be asked if you want to save or discard any changes you have made to the current Image View record.

The subject binder opens to the current Image View record in Data View. This record will be tagged with the letter 't' in the record list to identify it as the current Image View task record. This record cannot be modified while in Data View, and will display: **View only: record in use by Image View** in the message window at the bottom of the screen. The switch button, now labeled [Switch to Image View](#), can be used to return to the current Image View record and continue with data entry when you are finished reviewing other records in Data View.

Record Locking in Image View

Each set of CRF pages retrieved using the 'Automatic' or 'Manual' method is locked by the user who selects them. This is a lock on the image ID, not on the keys, which may at this point be blank or incorrect. These image locks prevent other users from trying to enter the same new pages in Image View. In large studies, with hundreds of pages arriving each day and several users working together to perform new data entry, it is best to minimize the number of pages that each person retrieves at a time. We recommend getting 1 document at a time.

When entering these records a record level database lock is requested for the key fields (ID, visit, plate) as soon as you move into a non-key field. You will not be able to change data or metadata, or save the record, if someone has the subject binder locked in Data View, or if someone is currently entering another record with the same 3 keys in Image View. However, it is possible for multiple users, all working in Image View, to simultaneously enter new data records with different visit and/or plate numbers for the same subject ID.

The only difference between EDC Data Entry and entering a set of records from submitted CRFs is that EDC Data Entry records do not have images and thus do not have image locks.

While working in Image View it is possible to switch to Data View to review and/or modify other records for the same subject ID. When you select **Switch to Data View** the record level database lock acquired on the key fields in Image View is released, a Data View subject level lock is immediately requested, and the subject binder is then opened to the same page that was being entered in Image View. If the subject ID lock is obtained, enter Data View in Edit mode with the lowest write level; which means that existing records which are modified and saved will remain at their current workflow level, and any new data or metadata data will be saved at the lowest write level.

If the subject ID lock cannot be obtained, Data View can still be accessed in View Only. However, because the record level database lock was released it is possible that upon returning to Image View further data entry will be prevented due to another user now having the database lock on that record.

If the subject ID lock is obtained on switching to Data View, any record in the subject binder can be modified (provided you have modify permission) except for the originating Image View record, which will be displayed in View Only mode. This record must be entered in Image View. You can easily return to it by selecting **Switch to Image View** that takes you back to this record in the Image View record list.

When a new record is saved in Image View and you move to another record, the database lock is released and the record becomes available to other users. All saved data records remain in the Image View list until they are released or the next set of new records is retrieved. This facilitates returning to a previously entered record to review or modify it. But remember that it is possible to discover that another user has modified or even deleted the record since you last saved it.

Image View Menus

This section describes the options available under the menu labels Select and Plate in the application menubar. Only those options that are unique to Image View are included. All other menus and options are the same as already described for Data View.

The Select Menu

The **Select** menu is used to select pages from the new record queue for data entry. The options include:

- [Automatic Retrieval](#) - as described above this dialog is used to specify how records are assembled for data entry.
- [Manual Retrieval](#) - use this option to display the list of records awaiting data entry and manually select those you want to enter next.
- [EDC Data Entry](#) - use this option to build a set of blank records for data entry from hardcopy CRF pages held outside of **DFdiscover**.
- [By Task](#) - this option allows users to select a predefined new data entry task.

- **Define Image Tasks** - use this option to specify a task for new data entry, including record selection rules, grant users/roles permission to use the task, user instructions, etc.
- **Export Tasks to Local File...** - export predefined image tasks to a local plain text file.
- **Import Tasks from Local File...** - import image tasks from a local plain text file.
- **Next Set** - this option applies the current record retrieval specifications to assemble the next set of records for new data entry.
- **Previous Set** - this option allows users to return to the previous set of records, but only records still remaining in the new queue will be displayed; any already entered or now in use by other users cannot be accessed.

The Plate Menu

The **Plate** menu includes the following options:

- **Save** - this menu item has pull rights for 'Final', 'Incomplete' and 'Pending' which are equivalent to saving changes using the buttons at the bottom of the screen.
- **Revert** - undoes all changes to the data, queries and reasons on the current page.
- **Review Images** - this option is used to review all of the images attached to the current data record, and is only available if the current record has more than one image.
- **Change Barcode** - as described above this dialog is used to make corrections to the values of barcoded key fields.
- **Delete This Page** - this option deletes the current image from the new image queue. If the image and its corresponding data record have been entered and saved to the database, returning to the image entry in the new record lists and then deleting the page will prompt you for both a reason for the deletion and your password. If logged in with Microsoft, click **Sign with Microsoft** to authenticate with your Microsoft account to complete the delete process.
- **Context** - this option shows the arrival date and time, and image sender ID of the current CRF page
- **List All Outstanding Problems on This Page** - lists each field with a problem on the current page including: required fields that are blank, illegal values, outstanding queries and rejected reasons
- **List History of All Changes on This Page** - report all changes made to data fields on the current page.

List View

List View is a read-only, spreadsheet-like presentation of study data. List View provides functionality to export data in various formats including Excel. List View also provides two ways of looking at your data - by Plates & Metadata or by Modules. List View is the only view that presents data in a module-based view.

As in all other views, what you see and what you can do depends on your user role and permissions for the current study.

Plates & Metadata: In Data View only one data record is displayed at a time. In List View all data records for a selected plate can be displayed at once. Each row is a data record and each column is a data field. This view is useful for comparing data records, searching for particular values, or scanning for data problems. Outlier values can be identified by sorting the spreadsheet on any column - click the field name at the top of a column to sort.

Plate Number	Visit Number	Subject	Visit Date	CRF not administered	1. When was last date you took pills?	1. When was last time you took pills?	2. Did you take the tablet every day?	2a. Reported missed days	2a. Actual missed days	2b. F number
1	110	010	250001	01/OCT/2016	Unchecked	01/OCT/2016	09:00	No		
2	110	010	350001	01/OCT/2016	Unchecked	01/OCT/2016	06:00	Yes		
3	110	020	350001	29/OCT/2016	Unchecked	29/OCT/2016	06:00	Yes		
4	110	030	350001	25/NOV/2016	Unchecked	25/NOV/2016	06:15	No	04	04
5	110	040	350001	20/DEC/2016	Unchecked	20/DEC/2016	06:30	Yes		
6	110	060	350001	22/FEB/2017	Unchecked	22/FEB/2017	06:00	No	03	01
7	110	070	350001	22/MAR/2017	Unchecked	22/MAR/2017	06:15	Yes		
8	110	080	350001	30/APR/2017	Unchecked	30/APR/2017	06:00	No	04	04
9	110	090	350001	26/MAY/2017	Unchecked	26/MAY/2017	06:15	Yes		
10	110	100	350001	24/JUN/2017	Unchecked	24/JUN/2017	05:45	Yes		
11	110	110	350001	22/JUL/2017	Unchecked	15/JUL/2017	05:00	No	14	14
12	110	120	350001	21/AUG/2017	Unchecked	21/AUG/2017	07:00	No	01	01
13	110	010	350003	07/FEB/2017	Unchecked	07/FEB/2017	08:00	Yes		
14	110	020	350003	05/MAR/2017	Unchecked	01/MAR/2017	09:30	No	05	05
15	110	040	350003	02/MAY/2017	Unchecked	01/MAY/2017	21:30	Yes		
16	110	050	350003	31/MAY/2017	Unchecked	30/MAY/2017	22:00	No	03	03
17	110	060	350003	29/JUN/2017	Unchecked	28/JUN/2017	23:30	No	02	01
18	110	070	350003	23/JUL/2017	Unchecked	22/JUL/2017	21:30	No	01	01
19	110	120	350003
20	110	050	450001	21/NOV/2018	CRF not administered			0		
21	110	010	450002		CRF not administered			0		
22	110	010	450003		CRF not administered			Yes		
23	110	020	450003	14/NOV/2018	Unchecked	09/NOV/2018	12:12	0	12	30
24	110	040	450003	08/NOV/2018	CRF not administered			0		
25	110	010	450005	01/NOV/2018	CRF not administered			0		

Modules: In Module List View, all data associated with a module is displayed in a single spreadsheet view. Key information is provided in the first six columns followed by three module reference fields, then the user-defined data fields within the module. If there are fields that are not referenced on a particular plate, the unreferenced field cells are shown in grey. Modules that have not been used on any plate are ignored.

Plate Number	Visit Number	Subject ID	Module Name	Module ID	Module Instance	Group Identifier	Medical conditions or events	Line Number/MH Number	Medical History Term	Start Date	Ongoing	End Date
17	200	201	MH	5048	1		Yes					
18	200	201	MH	5048	2			20101	anxiety	00/FEB/2014	Ongoing	
19	200	201	MH	5048	3			20102	lipoma removal	15/NOV/2009	Unchecked	15/NOV/20
20	200	201	MH	5048	4			20103	elevated ALT	18/MAY/2015	Ongoing	
21	200	201	MH	5048	5						Unchecked	
22	200	201	MH	5048	6						Unchecked	
23	200	201	MH	5048	7						Unchecked	
24	200	201	MH	5048	8						Unchecked	
25	200	201	MH	5048	1		Yes					
26	200	201	MH	5048	2			20101	fish allergy	00/000/2006	Ongoing	
27	200	201	MH	5048	3						Unchecked	
28	200	201	MH	5048	4						Unchecked	
29	200	201	MH	5048	5						Unchecked	
30	200	201	MH	5048	6						Unchecked	
31	200	201	MH	5048	7						Unchecked	
32	200	201	MH	5048	8						Unchecked	
33	200	201	MH	5048	1		Yes					
34	200	201	MH	5048	2			20101	wisdom teeth removed	23/FEB/2001	Unchecked	23/FEB/2001
35	200	201	MH	5048	3			20102	seasonal allergies	00/MAY/1999	Ongoing	
36	200	201	MH	5048	4						Unchecked	
37	200	201	MH	5048	5						Unchecked	
38	200	201	MH	5048	6						Unchecked	
39	200	201	MH	5048	7						Unchecked	
40	200	201	MH	5048	8						Unchecked	
41	200	201	MH	5048	1		Yes					
42	200	201	MH	5048	2			20101	ADHD	00/000/1994	Ongoing	
43	200	201	MH	5048	3						Unchecked	
44	200	201	MH	5048	4						Unchecked	

Custom: In Custom List View, all data associated with a custom defined view is displayed in a single spreadsheet view. Custom views can combine data across multiple plates into a single record following the data selection criteria specified in the **Define Views** dialog. Custom Views are also available (for those who have access) in Reports View under DFdiscover Reports > Tabular Listings.

	SUBJID	DFSUBJECT_ALIAS	BRTHDAT	ENRDAT
1	250001	T2-A-1	12/DEC/1980	
2		T2-A-1		09/SEP/2016
3	250002	T2-A-2	20/DEC/1993	
4	250003	T2-A-3	11/DEC/1980	
5	350001		27/MAR/1958	
6				07/SEP/2016
7	350002		31/JUL/1982	
8	350003		15/APR/1976	
9				09/JAN/2017
10	350004		21/JUN/1962	
11	450001			
12	999001			
13	999002		12/MAR/1990	
14	999003			
15	999004		02/SEP/2018	
16	999006			

As in Data View, the cells in the spreadsheet can be color-coded to identify: illegal values (red), rejected reasons and outstanding queries (blue), pending reasons and query replies (orange) and approved reasons and query replies (green). Queries, reason and missing value code are displayed in the metadata panels when a cell is selected that has these attributes, and any images associated with a data record can be reviewed when a record with images is selected.

List View does not support data editing. Double-clicking any cell in the table switches to that data field in Data View where edits can be made (and saved). Clicking **Return to List View** in Data View takes you back to the original cell in List View. Any changes that are made to the data record, or to its queries and reasons, while in Data View are displayed when you return to that record in List View.

All data records are retrieved from the **DFdiscover** server when you select a new page in List View, so the spreadsheet is up-to-date each time you select a new page. Also, **DFExplore** retrieves the current version of each data record when you select it in the spreadsheet, again the record is up-to-date at that instant. However, changes made since the records were retrieved, arising from other users or batch edit checks, are not automatically displayed; some or all rows in the table may become out of date while you are viewing them. As needed, update all records in List View at any time using **Select** > **Refresh**.

User Preferences

The List View section of the Preferences dialog, available from **File** > **Preferences** can be used to customize the appearance of List View. Preferences can be

used to enable/disable field color-coding and text expansion, determine whether field codes, code labels, or code sub labels are displayed, select column labels (field Name, field Alias and prepend with field number), and select the display format for date fields. All selections made in the preferences dialog are study specific and are retained across **DFExplore** sessions.

Navigation

To display the data records stored in the study database for a particular CRF page or module, select it from the list in the left panel. Within the data table you can select any cell with a mouse click, use the left/right keys to move across the fields in a data record, and use the up/down keys to move across data records.

The default record sort order is ascending by subject ID and within subject ascending by visit number. The rows of the data table can be sorted on any column by clicking the column label. Each click toggles the sort order between ascending and descending. Use shift-click to sort on a second column, in the current sort order within the currently sorted column.

The keys (subject ID, visit, page) of the current record and the number of data records in the table are always visible in the upper-left corner. The workflow level at which the current record was last saved appears along with the date and time at the bottom. If a Help message has been defined for the current data field it is shown in the help message window, also at the bottom.

Working on a Task

If a set of task records was assembled in Data View it remains in effect on switching to List View; only those CRF pages or modules and data records that met the task criteria are displayed. To see all CRF plates in the page list and all data records in the data table select **Show** > **All Pages** and **Show** > **All Records** respectively. To see all modules and all data records, select **Show** > **All Records**.

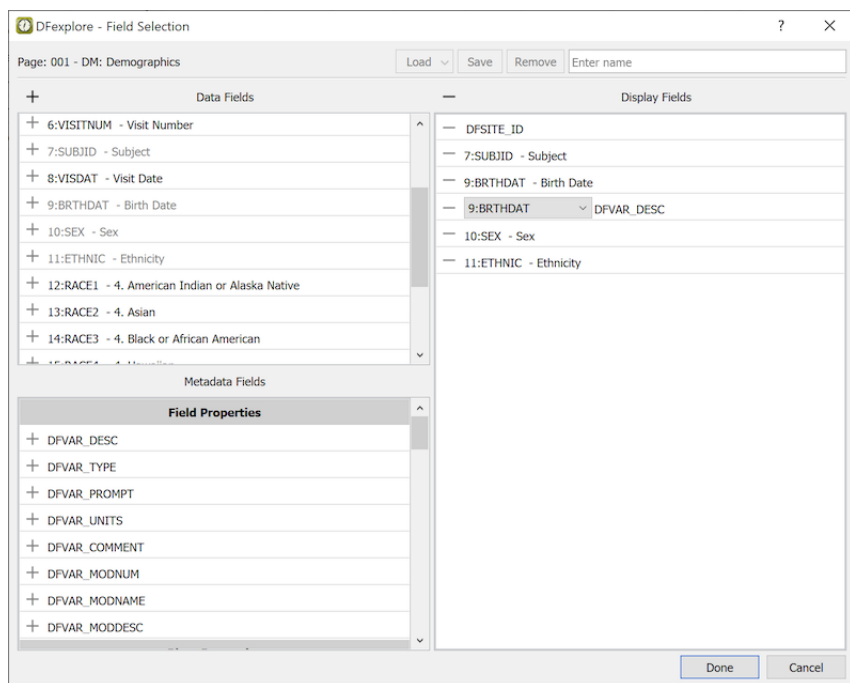
This does not cancel the task set. Task records can still be identified by the T icon that appears on each task record in the data table.

To cancel a task and see all data records choose **Select** > **All Records** in List View or Data View.

Selecting Data Fields

To select a subset of the data fields, or to include metadata fields, on the current plate or module, select **Select** > **Field Selection**. The field selection dialog has 3 main sections:

- **Display Fields:** The fields that have been selected for display in List View and/or for export.
- **Data Fields:** Fields from the current plate or module.
- **Metadata Fields:** Metadata from the set of fields, module, plate, page, visit, image, site, subject and study properties.



Fields can be selected for inclusion by clicking the plus icon (+) beside each field or by using drag and drop to add them to the **Display Fields** list. Click the plus icon at the top of the **Data Fields** list to select **all** fields of the selected plate or module, in their default order. Fields can be reordered using drag and drop within the **Display Fields** list.

Once added, individual fields can be removed from the **Display Fields** list by clicking the minus icon (-) beside each field. All fields can be removed from the **Display Fields** list by clicking the minus icon at the top of the **Display Fields** list.

Metadata Output Options

In addition to plate or module List view data, study metadata can be included. Metadata available for the selected plate or module is displayed in the **Metadata**

Fields list. Metadata fields are grouped into categories: Field Properties, Module Properties, Plate Properties, Page Properties, Visit Properties, Image Properties, Site Properties, and Study Properties.

Metadata fields can be selected using the plus sign beside each field or using drag and drop to add them to the **Display Fields** list. Once added, metadata fields can be removed from the **Display Fields** list using the minus icon beside each field. Fields can be reordered using drag and drop within the **Display Fields** list.

Several metadata keywords, DFVAR_DESC through DFVAR_COMMENT, as well as any custom properties at the field level, or at the module level when a plate is selected, are properties of each data field. Use the field drop-down list to further indicate for which field the property is requested. In the example, metadata DFVAR_DESC (the field description) is selected for the field BRTHDAT.

Custom properties at the study, plate, module, and variable level are included with other study metadata where values have been defined for the selected plate or module. Further details on custom properties can be found in [Study Setup User Guide, Custom Properties](#). The complete list of metadata fields and their meaning can be found in [Programmer Guide, DFexport, Including Metadata in Output](#).

Searching Data Records

The Search dialog, available from **Select**, can be used to find records within the current plate or module that meet specified criteria. If the **Filter** option is selected the record list is reduced to those records that meet the search criteria when selecting **Filter** at the bottom of the dialog, otherwise this button is replaced by a **Find** button, and the focus simply traverses those fields that meet the search criteria each time the button is pressed.

The Search dialog can also be used to add data records from the current plate or module into a Task set. After entering the record selection criteria, click **New Task** to display a task confirmation dialog (for Mode and Edit checks options) after which the selected records are flagged with the task icon to show that they belong to a new task set. **Add to Task** becomes active and can be used, after entering a new set of record selection criteria, to add more records to the current task set. This can be repeated as necessary to build a task set.

In this example, the current record list is filtered to show only those records for which: fields 8-24 are illegal or blank but required, site is 35 and workflow level is 2-7.

After specifying the search criteria, click **Filter** to start the search. A dialog appears showing the number of records that meet the search criteria and asking for confirmation before filtering the record list to display only these records.

To be selected records must meet one or more of the criteria specified in the **Data Fields** section and all of the criteria specified in the **Data Records** section.

To undo a Filter and display all data records for the current plate or module, select **Show** > **All Records**. To undo a Task and remove the 't' icon from all records select **Search** > **All Records**.

Search can be performed using multiple criteria across multiple plates by clicking **...** next to the **Subject** field to open another dialog for [Selecting Subjects based on Criteria](#).

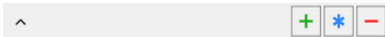
The Search dialog also includes an expression editor for creating simple algebraic statements describing the desired data records. Click **...** next to the Expression field. Expressions can be entered directly in the text widget or by clicking the Fields, Symbols, Codes and Functions in the appropriate order. Details are described in [Expression Editor](#).

If the expression editor does not have the capabilities you require, searching can also be performed using a standard or custom program specified in the 'By Program' option in the Search dialog as described in [Task Definition by Program](#).

When searching 'By Program' the Filter option must be enabled. When **Filter** is clicked the record list is reduced to show only those records identified by the program. If in addition to the 'By Program' option the 'Expression' editor or any of the other options in the 'Data Records' section are used, records are selected only if they meet all of criteria specified by all of these options. If any of the 'Data Fields' options are used the set of records selected is further reduced to include only those records that meet at least one of the field level criteria.

Saving Defined Views

List views consisting of specified data fields, field order and record selection criteria can be defined for use by specified users and/or roles using **Select > Define Views** to display the **Define Views** dialog. List views can also be accessed via the list action buttons available at the bottom of the **Plates & Metadata**, **Modules** or **Custom** panels.



The actions, in left-to-right order, are define, edit, and delete a view.

The steps to define a view are:

1. Click **+**, click **New View** and then enter a name and description.
2. Select the plate or module and data fields, in the desired order. If no fields are specified all fields in plate or module order are used.

Alternatively select custom and one of four options to use in creating a custom view.

- o Records that match subject and visit from all selected plates
- o Records that match subject from all selected plates
- o Records that match subject from any selected plates
- o Any records from the selected plates

Specify the plates and fields you want to include in the field list using the following syntax: plate:field,... Records selected from different plates with same subject ID will be merged to one single row. The merged records will not have visit info from other plates, except the first plate.

3. Select list view options. These override your Preference settings for List View when the view is selected.
4. Specify the roles and usernames to identify those who can use the view and those who own and can change it.
5. Specify the record selection criteria. If none are specified all data records for the plate or module are retrieved when the task is selected.
6. Click **...** next to the **Subject ID** field to open another dialog for [Selecting Subjects based on Criteria](#), which implements subject selection based on multiple criteria across multiple plates.
7. To form a new task set from the imported records, choose one of the **Create a new task set containing ...** options, and specify the task **Mode**, **Save Level** and whether to **Enable Edit checks** if you switch to Data View to review or modify a data record. If a new task is created, any previous task is canceled when the view is selected.

NOTE: This dialog is available to users who have 'List - Create Views' permission and can only be used by one person at a time.

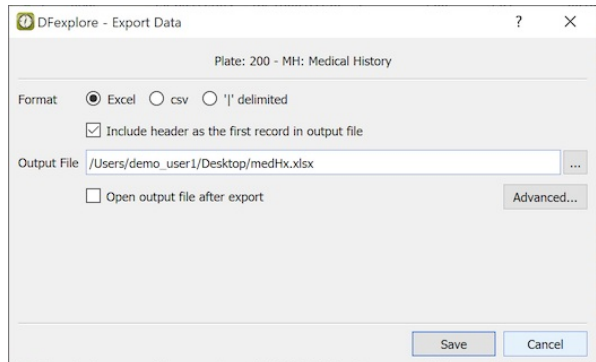
Once views have been defined, users can select a view by clicking **Open View** or using **Select > By Views**. This displays a dialog showing the predefined view names and descriptions. The current view, if any, is canceled when a new view is selected.

If no records meet the selection criteria for a selected view, the dialog reports that no records were found, the view is canceled, and the spreadsheet returns to its base state, showing all data fields and data records. The current view can be canceled at any time to return to the base state by selecting **Select > Cancel View**.

Canceling the current view does not cancel the current task set (if any). The spreadsheet returns to the base state showing all data fields and data records but any task records remain flagged. Clearing the current task set is a separate operation which is performed using **Select** > **All Records**.

Exporting Data Records

If you have permission to save data, the records currently displayed in List View can be written to a local file by selecting **File** > **Export Data**.



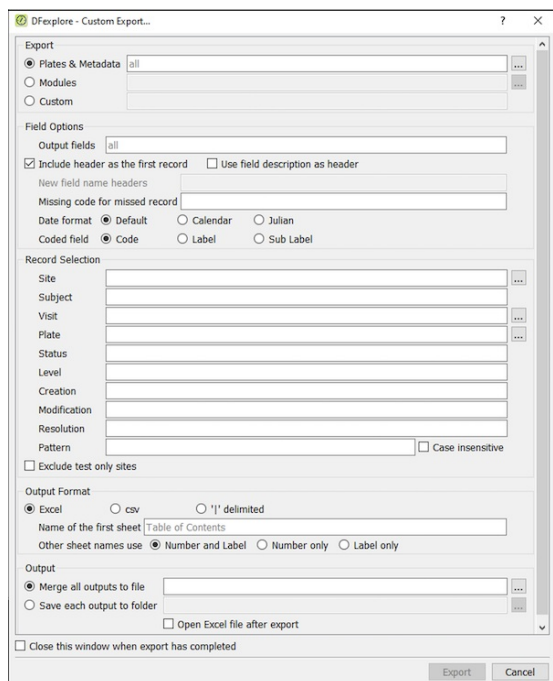
To export the data records displayed in the current List View specify:

- a field delimiter, or Excel format,
- if field names should be included as column names in the first output row, and
- an output file location.

Any data fields that have been hidden using **Select** > **Field Selection** are not exported. The message **Warning: Data will be saved with reduced fields** appears at the bottom of the dialog when this is the case.

Custom Data Export

If you have permission to save data, one or more plates, modules, or custom list views can be written to a local file in Excel, csv, or text format by selecting **File** > **Custom Export**.



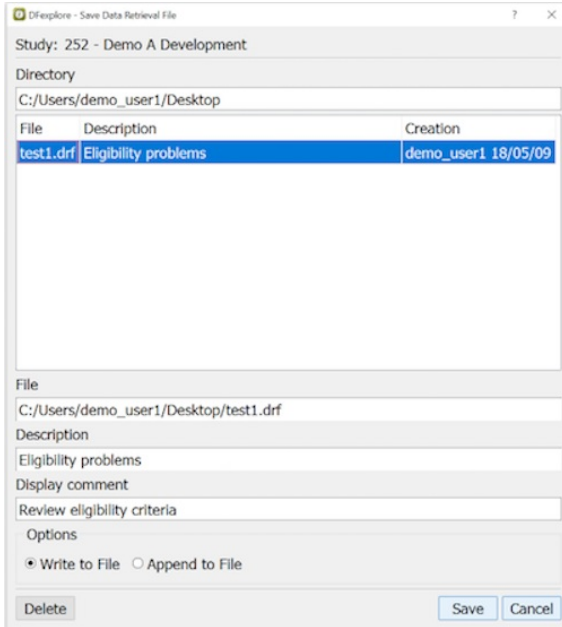
To export a custom set of data records, define the following:

- **Export:** Specify what data to export by selecting **Plates & Metadata**, **Modules**, or **Custom**. By default, all plates & metadata (queries, reasons, missed records, new image queue, query report) or modules will be included in the export; click ... to customize. When **Custom** is selected, the list of pre-defined views will be displayed, where one or more views may be selected for export.
- **Field Options:** For plates and modules, optionally customize the export's output fields (specify field numbers to include, or use NF notation to select fields relative to the last field in the record, for example: 2-NF for fields 2 to the last field inclusive, NF-1 for the second last field), header details, and output options for missed records, date formats, and coded fields. This section is not available for custom views, since the field options defined in the view are used, except for **Include header as the first record** and **Use field description as header**.

- **Record Selection:** For plates and modules, optionally customize which records to include in the export. The options are similar to those described in [Defining Tasks](#). Hover over each field to show a tooltip with details. Note that if **Status** remains blank, the export will include data and metadata of all statuses, including secondary and missed data records. To include metadata of all statuses and exclude secondary and missed data records, enter 'primary'. To include metadata of all statuses and exclude secondary records only, enter 'primary,missed'. For further details, refer to the record status description for each record type in [Programmer Guide, The study data directory](#). This section is not available for custom views, since the record selection options defined in the view are used.
- **Output Format:** Specify output as Excel, CSV, or pipe-delimited text file. For Excel, optionally customize the name of the first sheet and the sheet names used.
- **Output:** Choose whether to merge all outputs in one file or save each output (plate, module, or custom view) to its own file in a folder, and specify where to save the export file(s) on your device.

Exporting a Data Retrieval File

A Data Retrieval File (DRF) containing the key fields of the records currently displayed in List View can be written to a file on your local disk by selecting **File** > **Save Data Retrieval File** and using the dialog.



On entering an output directory/folder and pressing **Return** any existing DRFs in that location are listed.

Output can be written to a new DRF or an existing DRF can be selected and overwritten.

To export the records displayed in List View to a DRF specify:

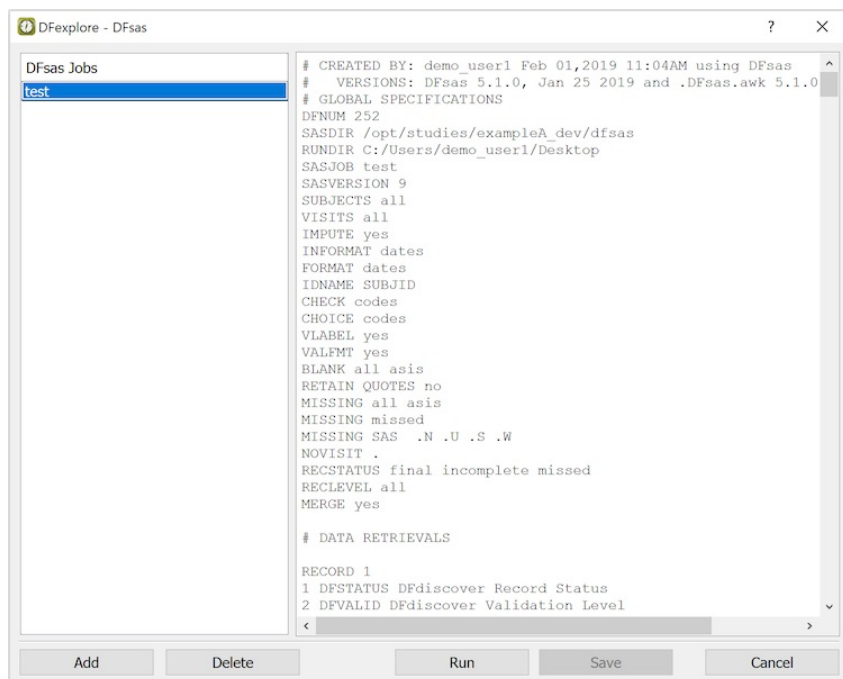
- an output file
- a short descriptive label for the DRF
- a comment for record level **DFExplore** help
- whether output overwrites or appends to the output file

An existing DRF can be selected and deleted using **Delete**.

Exporting SAS Data Sets

Users with permission can create and export data sets in SAS format to a file location on their local disk by selecting **File** > **DFsas** and using the dialog.

For instructions on creating and running DFsas jobs, refer to [Programmer Guide, DFsas: DFdiscover to SAS](#).

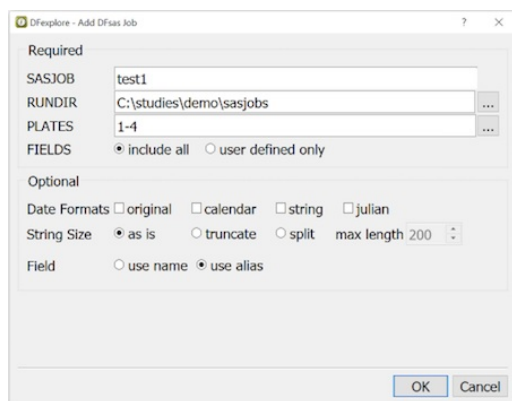


DFExplore works with DFsas job files located in the study dfsas directory on the **DFdiscover** study server. All existing DFsas job files are listed when the DFsas window is opened and the list is updated if any new jobs are added.

Selecting a job file loads it into the text window where it can be edited and saved back to the study server.

Selecting Run executes DFsas for the current job, which creates SAS job and data files and returns them to the local computer in a .zip file which is stored in the specified RUNDIR.

New DFsas job files can be created by clicking **Add** and using the dialog. The new job file appears in the text window and can be edited (as described in [Programmer Guide, DFsas: DFdiscover to SAS](#)) to create the desired DFsas job file.



The following can be specified when adding a DFsas job:

- **SASJOB** new DFsas job file name
- **RUNDIR** location on the local computer where SAS job and data files are stored.
- **PLATES and FIELDS** a DFsas job file can include some or all data fields on some or all study plates
- **Date Formats** optional, see below
- **String Size** long text can be truncated or split into multiple fields
- **Field** use name (default) or use alias when there are repeating modules and where field aliases are unique across the study.

If no plates are specified or 'ALL' is specified, all user defined plates in the range 1-500 plus **DFdiscover** plates 510 (reasons) and 511 (queries) are included in the DFsas job.

If no date format options are specified, dates are exported using the format and imputation specifications in the study setup. Alternatively, one or more of the following specifications can be selected:

- **original** - turns off imputation, outputs the value exactly as stored in the study database, and creates a date informat for SAS.
- **calendar** - performs imputation as specified in the study setup, converts 2 digit years to 4 digit years, and creates a date informat for SAS.
- **string** - turns off imputation, outputs the value exactly as stored in the study database, and creates a character informat for SAS.

- **julian** - performs imputation as specified in the study setup, converts the date to a [julian number](#), and does not create an informat statement as SAS does not need one for numbers.

Date imputation can be turned off for all dates, regardless of study setup specifications and regardless of which date formats are selected, by specifying 'IMPUTE no' in the global statements.

After saving a **DFsas** job file it can be executed at any time by selecting **Run**. A confirmation dialog appears with several options:

- **Force DFsas to include all specified plates:** Select this option if you want to include all of the plates specified in the DFsas job file, even if they do not currently contain any data records. If this option is not selected, a SAS data statement is only created for plates with data records.
- **Enforce role permission:** This option ensures that any permission restrictions defined in your role are applied to the export and is selected by default. For backwards compatibility with **DFsas** job files that rely on *DFexport.rpc*, this option can be deselected.
- **Exclude test only sites:** Use this option to exclude data from sites that are defined as Test Only.
- **Use subject alias:** Use this option to use the subject alias in place of the standard numeric subject ID.

After confirming that you wish to execute the selected DFsas job, **DFdiscover** runs DFsas on the study server and returns a .zip file, containing a SAS job file and a data file for each plate, to the specified **RUNDIR** on your local computer.

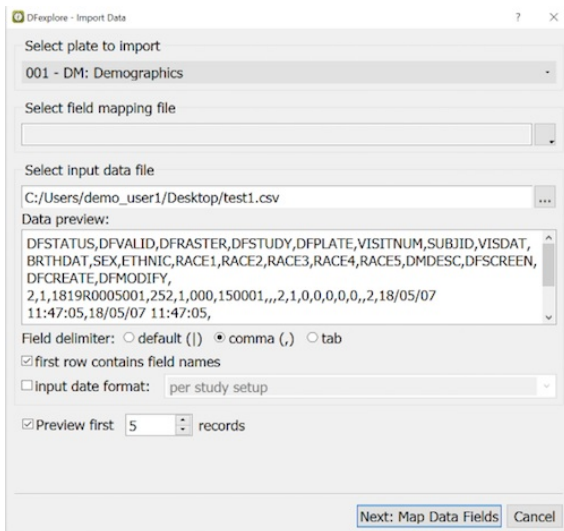
Importing Data Records

Data from labs and other sources can be imported to a **DFdiscover** plate by selecting **File** > **Import Data** in List View and following the steps listed below. Permission to use this feature must be granted in your study role.

Each imported data record may either create a new data record in the study database or replace an existing data record, having the same keys (ID, visit, plate). If a replacement record is imported all of the data fields on that record are replaced; it is not possible to replace only some fields while leaving others unchanged. If a replacement record is imported with status=7(delete) the database record is deleted.

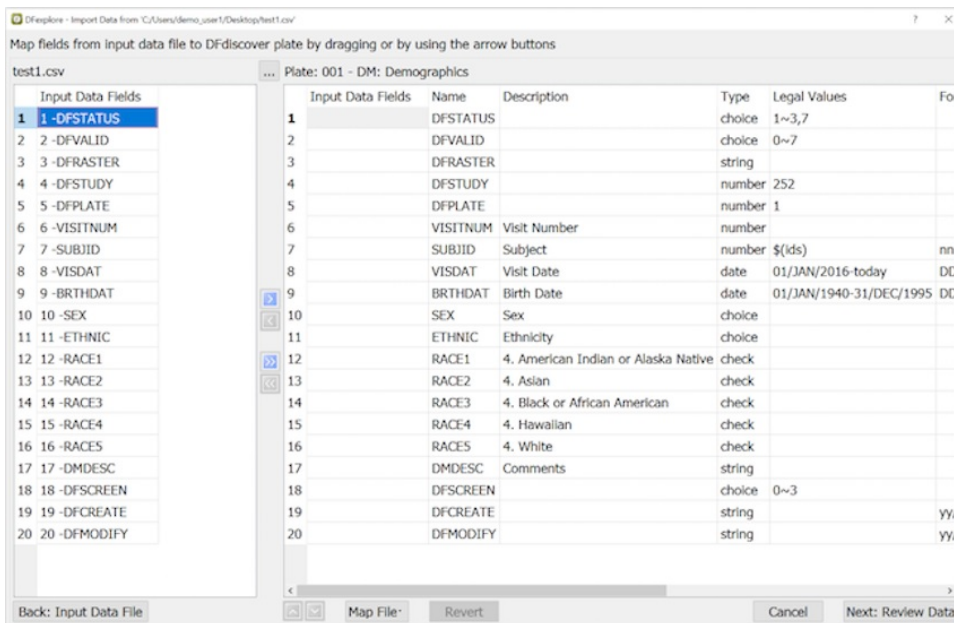
Import options may be set to add the reason 'Set by **DFexplore** Import' to any field that is changed, and to add automatic queries for missing and illegal values. All imported data records, plus any reasons and queries generated during import, are logged in the study audit trail by date, time and the username performing the import.

1. Select the Input Data File



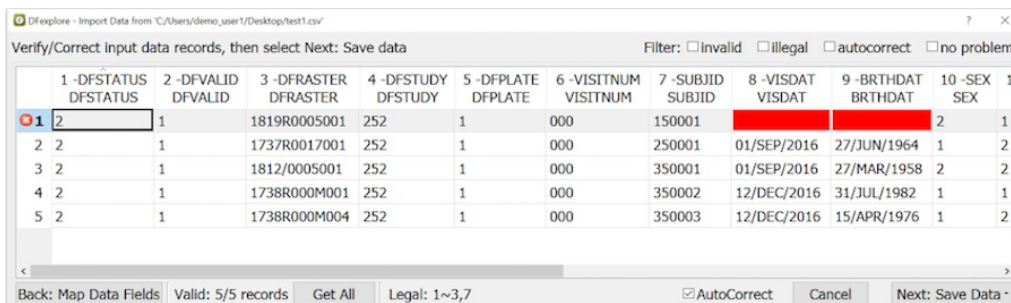
1. Select the import destination, i.e. the database plate.
2. If imports from the same source recur, the mapping of input fields to study database fields can be saved to a mapping file and reused.
3. When the input data file is selected the first 3 records are displayed in a preview window.
4. The input field delimiter must be one of: '|', comma or tab.
5. Having field names in the first input row is useful as an aid to field mapping, but it is not necessary.
6. If the date format used in the input data records differs from the format used in the study plate, choose the input date format to convert dates to the format used in the plate.
7. If the input file is very large, specifying a small number of records to preview allows you to quickly verify that the mapping and data appear correct before loading all of the input data records.
8. Click **Next: Map Data Fields**.

2. Map Data Fields



- To specify the mapping of input fields to database fields simply drag fields from the left panel to the right panel beside the corresponding Generic Name for the field in the study database, or use the buttons to move the current input field in the left panel to the next available slot after the current input field in the right panel. For example, clicking the right arrow button in the above dialog moves input field '1 -DFSTATUS' to Plate 001 field 1 DFSTATUS.
- The double arrows move all fields to the right panel, or back to the left panel, and can be used when all fields in the input records exactly match fields in the destination plate.
- Once moved to the right panel, input data fields can be matched with the correct generic name by dragging them with the mouse or by using the up and down arrow buttons.
- If the input file contains fields that are not included in the plate they can be omitted. It is not necessary to match and import all fields from the input records.
- If the plate contains fields that are not included in the input file a value can be specified under **Value if not mapped**, otherwise the field is blank in all imported data records. If the word today is specified for an un-mapped date field the current server date is inserted when the data records are imported.
- The only field that is required in the input file is the subject ID. The visit key field can be specified in the **Value if not mapped** column, as can any other field that you want to set to the same fixed value for all input records.
- Database records for a specified plate and visit can be deleted by importing a file that contains only the subject ID, and then specifying the relevant visit number and setting status=7 in the **Value if not mapped** column. No other fixed values are required.
- Plate fields DFRASTER, DFSTUDY and DFPLATE are set automatically and need not be mapped, but if they are then DFRASTER is treated as a key field which must match an existing record when importing replacement records in 'Replace' mode, and must equal 0000/0000000 when importing new records in **New** mode.
- The time stamps, DFCREATE and DFMODIFY, cannot be mapped. They are completed by the server when records are imported.
- During mapping click [Next: Review Data](#) to review the current mapping of data records, and **Back: Input Data File** to return to the mapping dialog.
- If other data files with the current mapping are imported in the future, the mapping can be saved to a file using [Map File](#) > [Save Current Mapping to File](#).
- If you forgot to specify a saved mapping file in the previous dialog it can also be selected in the mapping dialog using [Map File](#) > [Read Field Mapping from File](#).
- Click [Revert](#) to undo the current mapping and start over, or [Cancel](#) to abort the data import action.
- When mapping is complete, click [Next: Review Data](#).

3. Review Input Data Records



1. The spreadsheet previews a subset of the data records. Scroll left and right to verify that all fields have been mapped correctly.
2. Click **Get All** to load all remaining input records - specifically 5 as illustrated in the example.
3. Problem fields are identified by color: magenta for invalid values which prevent the record from being imported, yellow for values which are auto corrected on import, and red for illegal values, which are imported as is.
4. Check **AutoCorrect** to reveal how the yellow fields will be corrected.
5. Corrections can also be made by editing the values in the spreadsheet.
6. The data records can be filtered using the check boxes to display any combination of records with invalid, illegal and autocorrect values, or records with no problems at all.
7. Auto corrections that change the input value include:
 - Strings longer than the field store length are truncated
 - Numbers are truncated to the number of decimal places in the field format
 - Numbers greater than the field store length are imported as blank fields
 - Undefined codes in choice and check are imported as the field's blank value code
 - Invalid dates are imported as blank fields

Auto corrections that merely change the format of the input value include:

- String and date mapping is applied if specified in the field setup
- Leading zeros are added where required by the field format
- Leading zeros are removed where not required by the field format
- Leading '+' signs are removed from unsigned fields
- Input date format is converted to database format if specified in step 1

4. Get All Data Records

Verify/Correct input data records, then select Next: Save data Filter: invalid illegal autocorrect no problem

1 -DFSTATUS DFSTATUS	2 -DFVALID DFVALID	3 -DFRASTER DFRASTER	4 -DFSTUDY DFSTUDY	5 -DFPLATE DFPLATE	6 -VISITNUM VISITNUM	7 -SUBJID SUBJID	8 -VISDAT VISDAT	9 -BRTHDAT BRTHDAT	10 -SEX SEX
1	2	1819R0006001	252	1	000	350004	07/MAY/2018	22/JUN/1962	2
2	1	1819R0005001	252	1	000	150001			2
3	1	1812/0005001	252	1	000	350001	01/SEP/2016	27/MAR/1958	2
4	1	1737R0017001	252	1	000	250001	01/SEP/2016	27/JUN/1964	1
5	1	1738R000M004	252	1	000	350003	12/DEC/2016	15/APR/1976	1
6	1	1738R000M001	252	1	000	350002	12/DEC/2016	31/JUL/1982	1
7	1	1817R0001001	252	1	000	650000	23/APR/2018	01/SEP/1995	1
8	1	1803R0005001	252	1	000	999001	18/JAN/2018	18/FEB/1990	1
9	1	1810R000B001	252	1	000	999002	12/MAR/2017	12/MAR/1990	1

Back: Map Data Fields Valid: 9/9 records Legal: 1~3,7 AutoCorrect Cancel Next: Save Data

1. Click **Next: Save Data** to import the records to the study database or save them to a file on disk.
2. Only valid records displayed in the spreadsheet are saved. Confirm the setting of **Get All** and check the **Filter** options before continuing.

5. Save Data Records

1. After the **Next: Save Data** action, click **Save Records to Local Data File** for a file selection dialog. Alternatively, click **Save Records to DFdiscover Database** to present the **Import Records to DFdiscover Database** dialog.

2. Choose **Mode**.

- **New:** all input records have keys (ID,visit,plate) that do not already exist in the study database. Only new records are imported; any replacement records are rejected.
- **Replace:** all input records have keys (ID,visit,plate) that already exist in the study database. Only replacement records are imported; any new records are rejected.
- **Merge:** the input contains both new and replacement records. All are imported.

3. In the **Queries** section, it is recommended to resolve missing and illegal value queries if a legal value is imported, otherwise the queries do not correspond to the corrected values and will likely confuse users. None of the other query categories can be logically auto corrected in this way and thus remain unchanged.

4. In the **Queries** section, it is recommended to resolve missing and illegal value queries if a legal value is imported, otherwise the queries do not correspond to the corrected values and will likely confuse users. None of the other query categories can be logically auto corrected in this way and thus remain unchanged.

Queries can also be created automatically during import to flag missing and illegal values. If these options are selected existing queries are not modified or replaced, new queries are only created for fields that do not already have a query. Queries can also be created automatically during import to flag missing and illegal values. If these options are selected existing queries are not modified or replaced, new queries are only created for fields that do not already have a query.

5. Mark **Add Reasons to database fields that are changed by imported replacement records** to automatically add a standard reason, Set by DFExplore Import, to database fields that are changed when a replacement record is imported. Reason status can be set to Pending or Approved. To set Approved status, the user must have permission to approve reasons on the records being imported. If this is not the case reasons are created with the Pending status. Reasons that are created during import replace any existing reasons on the fields that are changed. The previous reasons are available in the audit trail, for example by selecting [Field] > [List History of All Changes on This Field].

6. Mark **Add Reasons to database fields that are changed by imported replacement records** to automatically add a standard reason, Set by DFExplore Import, to database fields that are changed when a replacement record is imported. Reason status can be set to Pending or Approved. To set Approved status, the user must have permission to approve reasons on the records being imported. If this is not the case reasons are created with the Pending status. Reasons that are created during import replace any existing reasons on the fields that are changed. The previous reasons are available in the audit trail, for example by selecting [Field] > [List History of All Changes on This Field].

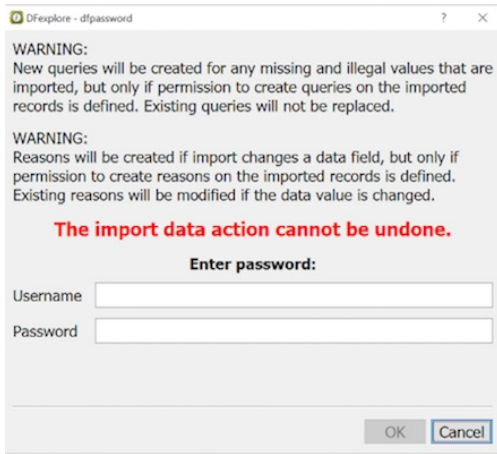
7. Mark **Task Set** to create a task that allows review of the imported data records when import is complete. The task set can contain all imported records or only those with illegal / missing values. This will be useful to review any queries generated during import. The task set must also include settings for **Mode**, **Save Level** and **Enable Edit checks**.

8. Mark **Task Set** to create a task that allows review of the imported data records when import is complete. The task set can contain all imported records or only those with illegal / missing values. This will be useful to review any queries generated during import. The task set must also include settings for **Mode**, **Save Level** and **Enable Edit checks**.

9. Click [Next: Import data].

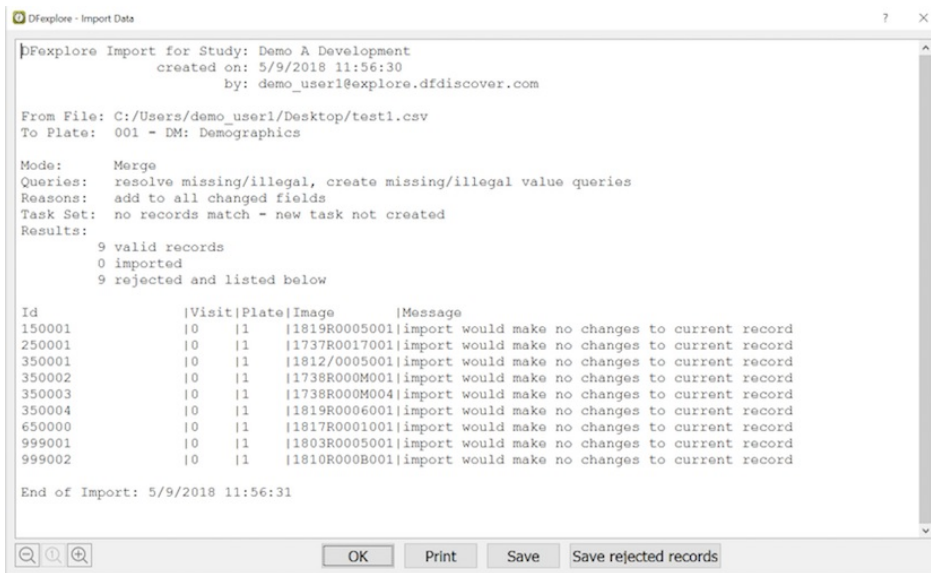
10. Click [Next: Import data].

6. **Confirm Import Data**



1. If the options to create queries and reasons were enabled in the previous dialog, two warnings will appear, as a reminder of the implication of those settings.
2. If the options to create queries and reasons were enabled in the previous dialog, two warnings will appear, as a reminder of the implication of those settings.
3. To start data import, enter user credentials for the study in the **Username** and **Password** fields. Click **OK** to proceed, or **Cancel** to return to the previous dialog. If logged in with Microsoft, click **Sign with Microsoft** to authenticate with your Microsoft account to confirm data import.

7. Review Results



1. The **Import Data** dialog appears when the import is complete, with a summary of the import specifications and results.
2. The **Import Data** dialog appears when the import is complete, with a summary of the import specifications and results.
3. If any records are rejected, they are displayed in this dialog along with the reason they are rejected. Click **Save Rejected Records** to save these records so that the problem(s) can be resolved and the import can be re-attempted.
4. If any records are rejected, they are displayed in this dialog along with the reason they are rejected. Click **Save Rejected Records** to save these records so that the problem(s) can be resolved and the import can be re-attempted.
5. We recommend keeping a record of all data imports by printing or saving this report. While the audit trail shows any new records and data changes made during import by: date, time and the username who performed the import, it does not distinguish between data entered and saved in Data View and records that were imported in List View.

Input data records may be rejected for the following reasons:

- The database record is currently locked by another user
- **Mode=Replace** but the record does not exist in the study database
- **Mode=Replace/Merge** and input keys match a database record but DFRASTER differs from the current database value
- **Mode=Replace/Merge** and input keys match a database record but input record is identical to the database record
- **Mode=New** but the record already exists in the study database
- **Mode=New** but DFRASTER is mapped and is not equal to 0000/0000000

- User does not have the permissions needed to import the record

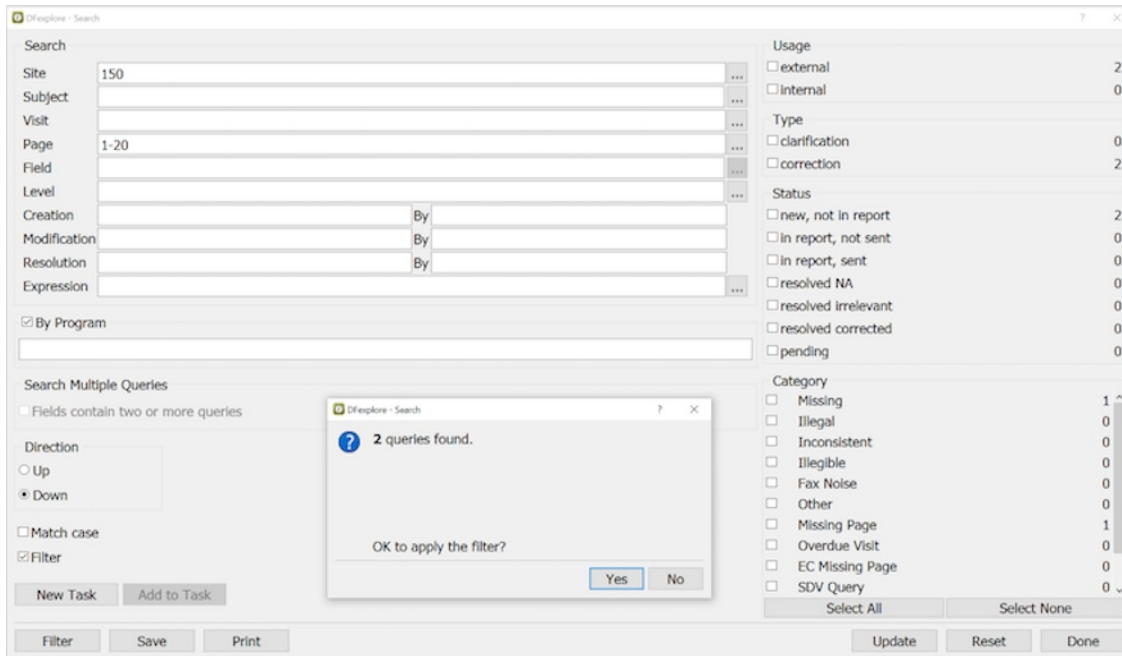
Metadata - Queries, Reasons, Query Reports and Missed Records

In addition to displaying subject data records List View also displays queries, reasons, returned Query Reports and records that have been classified as 'missed'. Users who have permission to see a data record automatically have permission to see queries and reasons attached to fields on that record. Permissions for Query Reports must be granted explicitly through plate 501, otherwise Query Reports do not appear in List View. Missed data records follow the same permissions as regular data records.

Changes can only be made in Data View. Double-clicking anywhere on a metadata record in List View switches the view to Data View with the focus on the field that was double-clicked. Click [Return to List View](#) in Data View returns you to the field that was double-clicked in List View.

For roles without "Show Hidden Fields" permissions and fields with Hidden/Masked property, no query or reason is displayed in List View.

Queries can be searched using [Select](#) > [Search](#). This dialog shows the number of queries that meet all of the current search criteria. The [...](#) next to the **Subject ID** field opens another dialog for [Selecting Subjects based on Criteria](#) which implements subject selection based on multiple criteria across multiple plates. After entering new criteria click [Refresh](#) to update the counts.



In this example 2 queries match all of the specified criteria.

Click [Save](#) or [Print](#) to output the criteria and counts shown in this dialog.

Click [Filter](#) to select these 2 queries and remove all others from the current list view.

Click [New Task](#) to put the data records with these queries into a new task set.

After clicking [Filter](#), new criteria can be specified to narrow the search further within the previously filtered set.

Records matching new search criteria can be added to a current task list by clicking [Add to Task](#).

If you submit Query Reports to the sites they may respond by writing directly on a printed copy of a report and submitting it back to **DFdiscover**. Returned Query Reports are not subject CRFs and thus are not displayed in a subject binder. They can however be processed in Image View, just like data records, and saved in the study database with key fields: ID equal to the Query Report number (composed of the site number and Query Report creation date), and Sequence equal to the Query Report page number. Any Query Reports that have been saved in this way can be reviewed in List View.

If you have permission to modify returned Query Reports you are able to correct any errors that might have been made when the key fields were entered. To make corrections, select [Select](#) > [Change Mode & Level](#) to set mode to anything except View, and then select [Plate](#) > [Change Keys](#) to display the **Change Keys** dialog.

Like subject data records, Query Report pages can be filtered using the **Search** dialog, and the current set of pages can be printed or saved in a PDF file by selecting these options from the **File** menu.

Workflow tasks can also be performed on Query Reports in List View. For example, new Query Reports are typically saved at level 1 when they arrive in Image View. Someone may then have the task of reviewing them and moving them to level 2 to indicate that they have been reviewed. To perform this task select [Select](#) > [Change Mode & Level](#) to set Mode to Validate and Level to 2. Next select [Select](#) > [Search](#) to find the Query Report pages that are currently at level 1. After reviewing each page, save it by selecting [Final](#) or [Incomplete](#). This moves the page to level 2. Use the search dialog again at any time to find the pages that currently have incomplete status.

List View Menus

This section describes the List view options available under the **File**, **Select**, and **Show** menus in the application menubar. The options available under the remaining menus have already been described for the Data view.

File Menu

The **File** menu is similar to all other views (data, queries, and reasons) with the exception of the following items:

- **DFsas...** - Users with permission can create and export data sets in SAS format to a file location on their local disk. Refer to [Exporting SAS Data Sets](#) for further information. For instructions on creating and running DFsas jobs, refer to [Programmer Guide, DFsas: DFdiscover to SAS](#).
- **Import Data...** - Users with permission can import data from labs and other sources to a **DFdiscover** plate with this feature. Refer to [Importing Data Records](#) for further information.
- **Export Data...** - Users with permission can export the data records currently displayed in List View. Refer to [Exporting Data Records](#) for further information.
- **Custom Export...** - Users with permission can export one more plates, modules, or custom listings at once. Refer to [Custom Data Export](#) for further information.

Select Menu

The **Select** menu is used to select the data records (rows) and data fields (columns) to be displayed in the List view table. The options include:

- **All Records ...** - cancel current task set (if any) and show all data records for the CRF page currently selected in the left panel of the List view dialog. When canceling a task set a new mode and save level can be specified in a pop-up dialog.
- **Field Selection ...** - select and arrange the data fields page to be displayed from the current page.
- **Search ...** - specify criteria used to find data records, reduce the rows in the List view table to those meeting the specified criteria, and/or to create a new task set.
- **By View ...** - select data records (rows) and data fields (columns) using a predefined view.
- **Cancel View...** - cancel previous By View selection to display all data records and data fields for the current page.
- **Define Views...** - define views for oneself and/or for other users.
- **Export Views to Local File...** - export predefined data views to a local plain text file.
- **Import Views from Local File...** - import data views from a local plain text file.
- **Refresh** - update all data records for the current page from the study server to get new records that may have been added or changes that may have been saved since the view was opened.

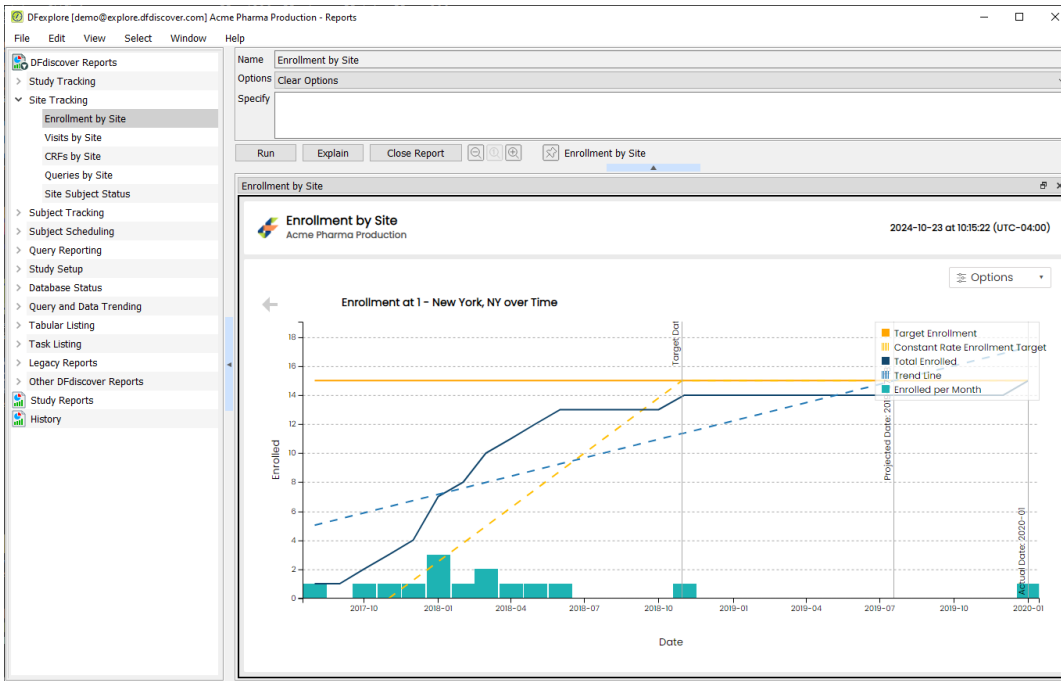
Show Menu

The **Show** menu is used to select the study page types and individual records to be displayed in the List view table. The options include:

- **All Plates** - show all page types defined for the study
- **Task Plates** - show only those page types included in the current task set
- **All Records** - show all data records for the currently selected page type
- **Task Records** - show only those data records included in the current task set

Reports View

Reports appear as an option under the View menu if you have been granted permission to run one or more of the standard **DFdiscover** reports or study specific reports. Reports can be updated and viewed within the Reports View and can be printed or saved to an Excel, PDF, HTML, Archive HTML, or text file. The Reports View is illustrated below.



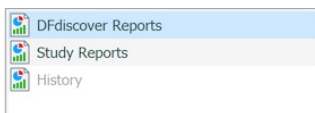
DFSTATUS	DFVALID	DFRASTER	DFSTUDY	DFPLATE	VISITNUM	SUBJID	VISDAT	REMOTEYN
2	1	2540/000C001	20	1	001	0		1
1	3	2249R0007001	20	1	000	3000	2022-12-06	0
2	1	2234/000K001	20	1	001	3000	2022-08-23	0
2	1	2249R0007008	20	1	002	3000	2022-12-06	1
1	1	2325R0003011	20	1	003	3000	2023-06-19	2
1	1	2325R0003012	20	1	004	3000	2023-06-19	0
1	1	2325R0003013	20	1	005	3000	2023-06-19	0
1	1	2325R0003014	20	1	008	3000	2023-06-30	0
2	1	2325R0003015	20	1	041	3000	2023-07-05	0

Reports in table format display a results total and pagination buttons at the bottom of the report. Users can navigate between pages by clicking or to advance and or to navigate back between a page or pages. By default, all rows of output are displayed. Use the Option `-limit \<#\>` to set a smaller total of rows.

Pagination is not available for reports containing multiple tables or both images (charts/graphs) and tables.

Report Types

Reports are generally categorized as one of 3 types. These 3 types are presented in the reports list. Clicking any type updates the reports list with the reports of that type.



- DFdiscover Reports:** All of the standard **DFdiscover** reports for which you have permission are listed. The standard reports are designed to address common trial management needs, like summarizing data management status for individual subjects and clinical sites. The **DFdiscover** Reports are themselves separated into two groups: legacy reports and standard reports. Legacy reports generate plain text output only. It is not possible to save the output from legacy reports as Excel. Standard reports generate HTML output and can be saved in different formats, including HTML, Archive HTML, PDF, Excel and Text. The HTML and Archive HTML output formats have the same content but the HTML content has references to external resources (like CSS

and JS) while Archive HTML is self-contained, without external resources.

Details on all standard reports are provided in the [Reports User Guide](#).

- 2. **Study Reports:** Lists the study specific reports, designed by programming staff at the trial coordinating site, to address needs not covered by any of the standard **DFdiscover** reports.

Details on all legacy reports are provided in the [Reports User Guide](#).

- 3. **History:** As each report is run it is added to the History list. You can review the output from any recently run report by opening this list and selecting the report. You can re-run reports from within the History list by selecting the report in the list and clicking **[Run]**. Unless changed, a selected report runs with the same options used the first time and then is also added to the end of the History list. If the report History list is saved, the options are also saved.

Tabular Listing

Tabular listing reports create tables from the data that is selected by previously defined views (see [Saving Defined Views](#)). Each view that is permitted is listed under the **Tabular Listing** heading in the reports list. Additionally, there are standard tabular listings that provide details about selected plates or modules or the information related to database keys. The **Module Listing** report, for example, combines the data and metadata specific to a selected module.

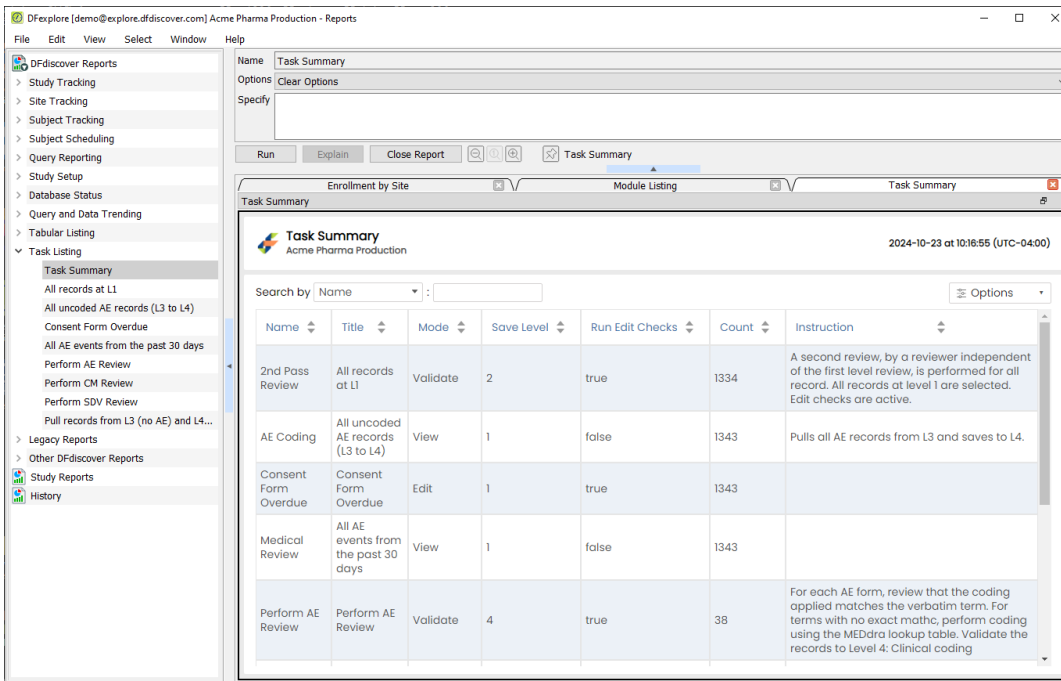
The screenshot shows the DFdiscover Reports application interface. The left sidebar contains a tree view with categories like 'Study Tracking', 'Site Tracking', 'Subject Tracking', 'Query Reporting', 'Study Setup', 'Database Status', 'Query and Data Trending', and 'Tabular Listing'. Under 'Tabular Listing', 'Module Listing' is selected. The main window displays the 'Module Listing' report for 'DFdiscover Solutions' on 2025-10-29 at 10:03:28 (UTC-04:00). The report shows 18 results, with the first few rows visible in the table below.

DFSTATUS	DFVALID	DFRASTER	DFSTUDY	DFPLATE	DFSEQ	SUBJID	DFMNAME	DFMID
1	1	2013R0001001	20	30	301	10001	AE1	5012
1	1	2238R0001001	20	30	302	10001	AE1	5012
1	1	2509R0005001	20	30	301	10003	AE1	5012
1	1	2509R0005002	20	30	302	10003	AE1	5012
1	1	2015R0002008	20	30	301	10004	AE1	5012
1	1	2509R0004001	20	30	302	10004	AE1	5012

Tabular listings provide a convenient way to share the results of defined views with others within the study team, via Reports View, or outside the study team by saving the output as HTML or Excel. Within Reports View any table row is clickable and changes the view to Data View where the complete matching data record is available for review or editing.

Task Listing

Every defined task appears under the **Task Listing** heading. As tasks are created, they are automatically added to this reports list. For convenience, a standard **Task Summary** report is always available and summarizes the key properties of each task, including the count of records that match the task criteria.



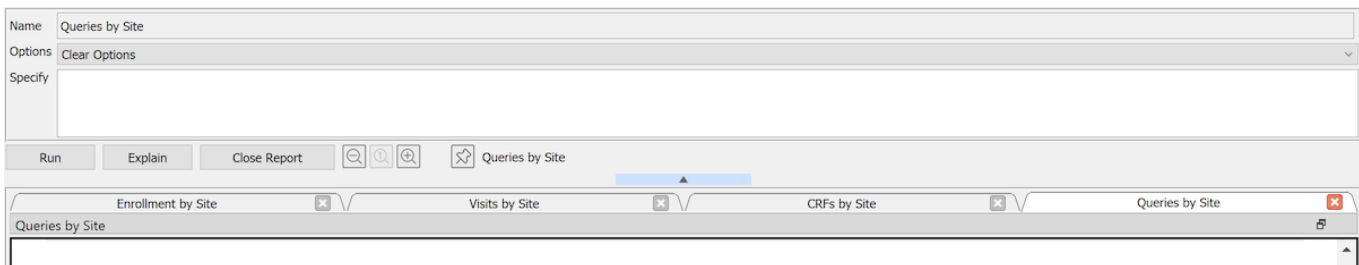
Shortcuts to perform the tasks listed in the Task Summary are available from Dashboard View.

Explain - Report Documentation

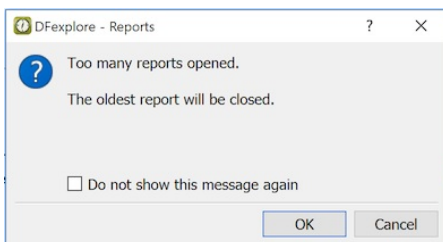
All **DFdiscover** reports include documentation that can be accessed by selecting the report name and then clicking **Explain**. The documentation generally includes a description of any options that may be specified before the report is run and an explanation of the report output.

Tabbed and Docked Windows

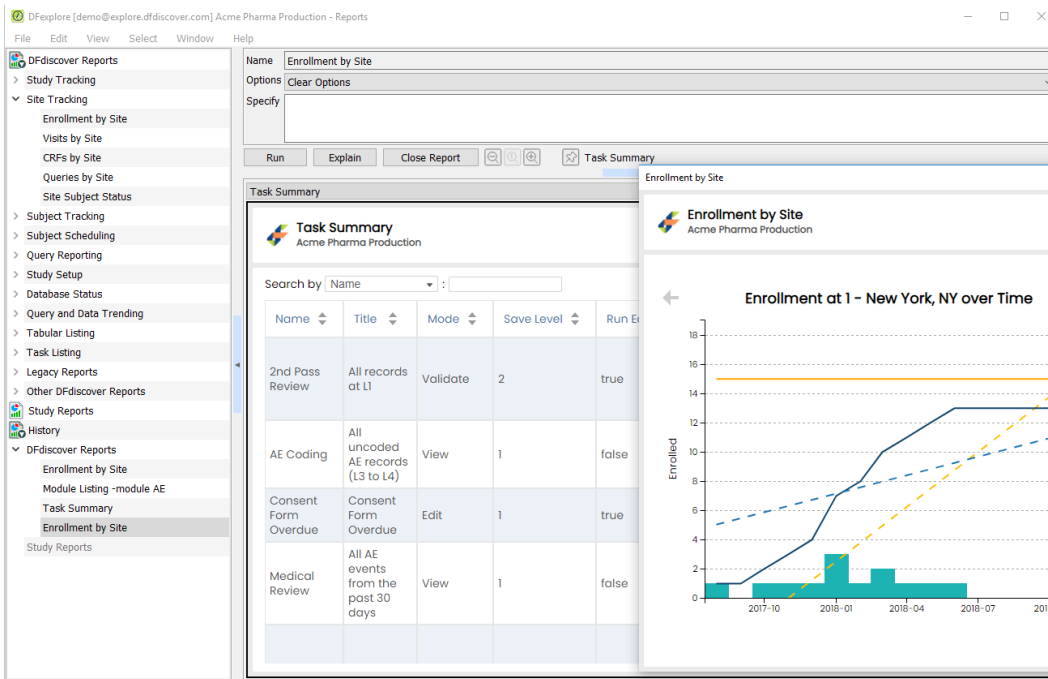
In **File** > **Preferences**, enabling the user preference **Each report run opens in a new tab** allows each report run (and explain action) to appear in a separate tab. Tabs appear in the "tab bar" at the top of the main report output window. Tabs can be re-arranged by drag and drop. Tabs can also be closed by clicking **X**.



Reports View is limited to a maximum of 25 tabs at once. Once 25 tabs are open, subsequent report runs display this warning and the oldest tab is closed.



Further, it is possible to undock and dock report tabs. Any tabbed window can be "grabbed" with the mouse and dragged out of the tab bar. This is an undocked report.

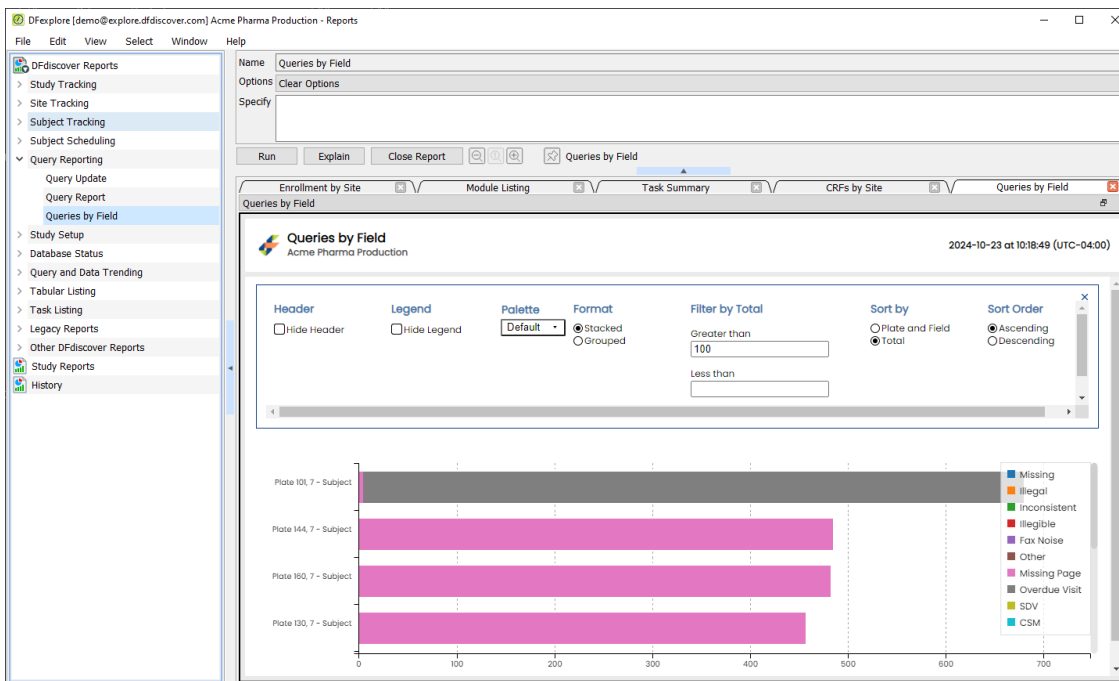


An undocked report can also be re-docked by dragging the tabbed window over top of the tab bar.

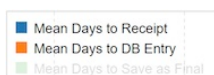
Interactivity

Dfdiscover reports include built-in interactivity - output can be manipulated and displayed in diverse ways without re-executing the report. Some of the interactivity options include:

- **Options drawer:** The options drawer is opened by clicking on the options tab (Options). Several appearance settings and behaviors can be changed in the options drawer. Each report has a common option to display/hide the header, plus its own unique settings. When the drawer is open, the reports window output is updated immediately whenever a setting is changed. When no further changes are needed, click the options tab () to close the drawer.



- **Display/hide elements:** The visibility of elements in a graph can be toggled by clicking the corresponding element in the graph legend. Clicking an element once turns off visibility and clicking it again turns on visibility.



- **Display graph values:** By hovering the mouse pointer over a graph or chart element, it is possible to inspect the data value(s) in that element.



- **Report sub-views:** More info for a report is available by clicking a chart or graph element. In some cases, this action creates a sub-view of the current report, switching the displayed content. From the sub-view, you can return to the main report window by clicking the return arrow ().
- **Zoom contents** The contents of any docked report can be zoomed using the zoom controls (). From left-to-right, the actions are zoom out, return to normal (no zoom) and zoom in. For undocked reports, keyboard shortcuts are available. They are **Ctrl** + **[-]** (zoom out), **Ctrl** + **[0]** (no zoom) and **Ctrl** + **[=]** (zoom in). On macOS, as with all keyboard shortcuts, replace **Ctrl** with **Command**. These keyboard shortcuts are also available for docked reports.

Report Options and Database Permissions

Many legacy (and a few **DFdiscover**) reports include options that can be used to alter what the report produces. For example, *DF_PTcrfs* (which displays a summary of CRF status for subjects) includes options to specify which subjects, visits and CRF pages are to be included. Report output also depends on your database permissions, and includes only information based on data records you have permission to read.

Selecting the Options widget displays the entire options list. Selecting an option from the list copies it to the Specify window with the part you need to change highlighted. For example, the **DF_PTcrfs** option used to limit the output a subset of subjects is: `-i \<#, #-#\>`.

Name	DF_PTcrfs: Display available CRF information for subjects
Options	Clear Options
Specify	Clear Options
	-c <#, #-#\> ...Select only subjects from specified sites
	-i <#, #-#\> ...Select only subjects with specified IDs
	-p ...Execute DF_XXkeys, but only list plates with problems
	-x ...Do not execute DF_XXkeys
Run	-l <# chars> ...Set maximum length of output line to #chars (default # = 80)

When this option is selected it is copied to the Specify window with `\<#, #-#\>` highlighted.

Name	DF_PTcrfs: Display available CRF information for subjects
Options	-i <#, #-#\> ...Select only subjects with specified IDs
Specify	-i <#, #-#\>

Changing this to 99010-99020 yields the option `-i 99010-99020`, which limits the output to those Subject IDs.

Running Reports

Click **[Run]** to run the report with the current options and display the results in the main (output) window. If the preference **Each report run opens in a new tab** is selected, a new tab is created and the report output is presented in that new tab. Otherwise, the output from each report run replaces the output from the previous report.

By switching to the **History** list you can select and review the output from all reports you have run since login. The run history is not saved between logins. Use **[Select]** > **[Define Report List...]** to create a list of commonly used reports that is available across logins (see [Saving Report Lists](#)).

The current output in the report window can be printed or saved, in PDF, HTML, Excel or text format, by selecting any of these options from the **File** menu.

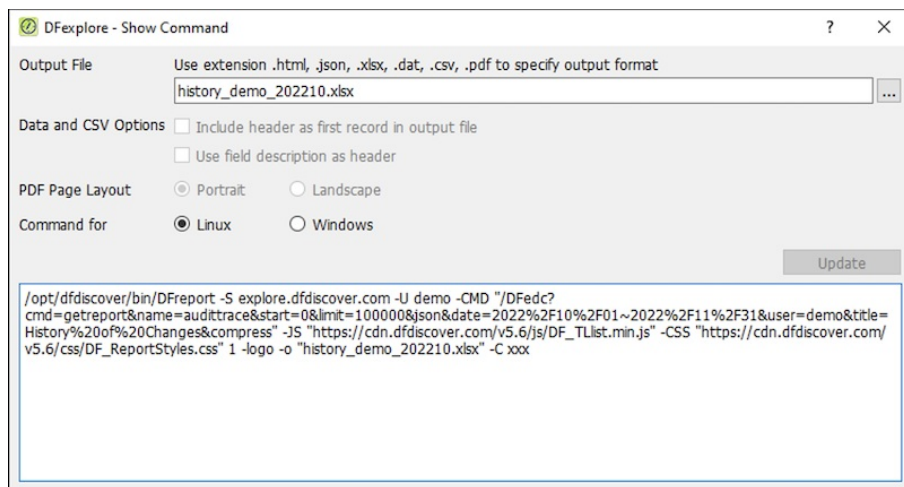
Running Reports outside of DFExplore

Reports can also be run outside of **DFExplore**. For example, the report can be manually executed from a command line or a script, or scheduled to run at a defined time via a scheduling facility like **crontab**. Select **[Help]** > **[Show Command]** to display the complete report command. If needed, customize the command using the following options:

- **Output File:** Specify the location, file name, and format of the output file. The file extension determines the format of the output file. Note that if the selected report does not support the specified format, an error message will display after clicking **[Update]**.
- **Data and CSV Options:** When .csv or .dat file extension is specified, you may choose to include the header as the first record in the output file and use the field description as the header rather than the field name.
- **PDF Page Layout:** When .pdf file extension is specified, you may choose portrait or landscape layout.
- **Command for:** Select the operating system to be used when running the command.


Click **[Update]** to update the command in the panel below with your selected options.

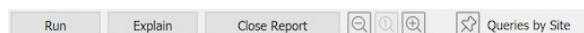
Copy the command and paste as needed. Remember to supply the user password in the report argument `-C xxx`, or use **DFpass** to store the user password for subsequent lookup.




Adding Reports to the Dashboard

DFExplore includes a convenient "pin" action that adds the report with current focus to the Dashboard View.

Any report can be added to the Dashboard View ("pinned") by running it first (or selecting it's tab so that it has the focus) and then clicking the pin button () which appears to the right in the row of report action buttons.



Using this feature, it is easy to customize the default appearance of the Dashboard View. Which reports have been pinned is remembered across invocations of **DFExplore** so these reports also appear in Dashboard View when **DFExplore** is restarted in the future.

If the report has previously been pinned or is already included in the Dashboard View as a result of view customization, the button appearance is inverted (), showing that the report is already pinned. When this is true, the report cannot be pinned again. To update the report in the Dashboard View (perhaps because options have been changed), first remove the report from the Dashboard View, run it again and then pin it.

Saving Report Lists

A list of commonly executed reports can be saved for later execution by specified users and/or users with specified roles. You can also specify the user and roles that are permitted to own and thus modify each report list you define. The permissions granted at this level do not over-ride the permissions defined in user roles. If a user lacks permission for any report in a report list, the entire list is unavailable in **DFExplore**.

A report list is defined using **Select** > **Define Report List...** to access the dialog. Previously defined report lists can be accessed by selecting **Select** > **Report List...**. Reports and report options may be added to a report list manually, or the current History list can be used as a starting point and then modified.

To access a previously defined report list, use **Select-Report List** and select the desired report list.

All reports can be executed in the order they appear in the list by choosing **all reports** and then clicking **OK**. The output from each report is added to the current History list.

Reports can also be executed one at a time by choosing the **selected report** option, selecting a report from the list, and then clicking **OK**.

Report Output Formats

Select **File** > **Save Output As...** to write the report output to a file. Different formats are available.

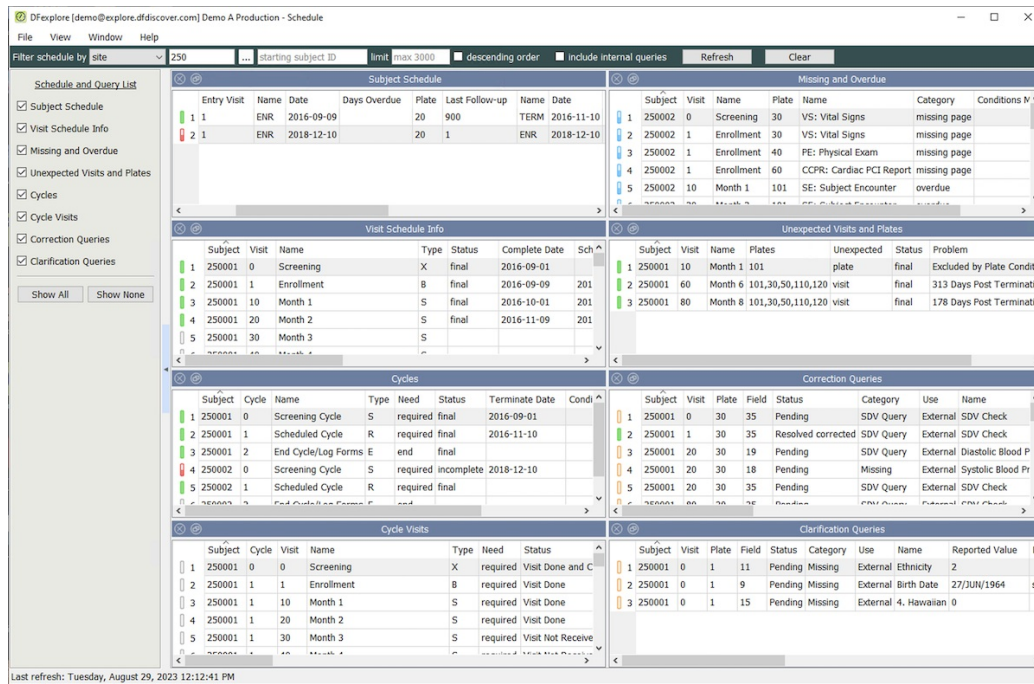
HTML	The report window output is in standard HTML format and contains external references to CSS and JS resources. The saved HTML can be shared and the interactivity of the content is preserved so long as the viewer has an internet connection. Without an internet connection, the report HTML appears as a blank window.
Archive HTML	The report window output is in standard HTML format and has all of CSS and JS resources contained within the file. The saved HTML can be shared and the interactivity of the content is preserved. No internet connection is needed to view the HTML. This option is not available for legacy reports.
PDF	The HTML content of the report output window is saved as a PDF. There is no interactivity in this format.
Excel	Standard DFdiscover reports can save their raw data to an Excel file. There is no visualization applied to the data - the data itself is saved. This option is not available for legacy reports.
Text	Save the output from report in a plain text format. For standard reports, the raw data is saved; for legacy reports, the "formatted" text output of the report is saved.

Schedule View

DFdiscover is able to calculate and report the current schedule for any subject in the study. This greatly simplifies the task of monitoring individual subject data for

missing pages and overdue visits.

The primary interface is Schedule View.



This chapter does not describe how scheduling is defined in **Dfdiscover**. If you are not familiar with scheduling terminology, or scheduling in general, an excellent reference can be found in [Study Setup User Guide, Subject Visit Scheduling](#).


Features

Schedule View displays all schedule information for permitted sites or subjects. The information is shown in several different schedule and query lists, namely:

Subject Schedule	Display an overall summary of the schedule, one record per subject. Per subject, the summary reports the number of outstanding queries, and the dates of entry visit, last follow-up visit and the next follow-up visit, if any.
Visit Schedule Info	Display a detailed summary of the schedule, one record per subject visit. For each subject, each scheduled visit is reported, including completed and not yet completed visits.
Cycles	Display a summary of the schedule, one record per subject cycle. Each cycle is reported with the cycle status, when it completed and what condition, if any, caused the cycle to become required.
Cycle Visits	Display a detailed summary of the schedule, one record per subject visit cycle. Where cycles occur, report the status of the visits within each such cycle.
Missing and Overdue	Display a list of all pages that are required yet missing, as well as all scheduled visits that have not occurred and are identified as overdue.
Unexpected Visits and Plates	Display a list of all CRFs and visits that have been completed but based upon the schedule are not expected.
Correction and Clarification Queries	Display a list of all outstanding queries, separated in two lists based upon their correction or clarification property.

Interactivity

The Schedule View is interactive.


1. Double-click a row in any list to switch to Data View. The subject, visit and plate identifiers are used to select the matching record in the database, making it current. Further review or editing of the visible record is then possible, as permitted by the role definition. Click the schedule view icon, , to return to Schedule View.
2. By default, the contents of each list are sorted in increasing order of Subject ID. To change the sort order, click on the heading of the column used as the sort key. Each click reverses the previous sort order.

To control which lists are displayed, and updated, use the list control:

Schedule and Query List

- Subject Schedule
- Visit Schedule Info
- Missing and Overdue
- Unexpected Visits and Plates
- Cycles
- Cycle Visits
- Correction Queries
- Clarification Queries

Show All Show None

Within any list, click the list window control, , to expand the contents by detaching the list from the main window. Click the control again to restore the list to the main window.

Filtering Results

The contents of Schedule View are aware of the current subject open in Data View. If a subject binder is open and **View** > **Schedule** is selected, the schedule and query lists are automatically refreshed using the ID of the current subject. If no subject binder is open, the view opens to show the previous schedule, if there was one, or is blank.

To control the contents of Schedule View, use the filter panel.

Filter schedule by **subject** starting subject ID limit max 3000 descending order include internal queries Refresh Clear

With no filtering specified, as shown, all permitted subjects (up to a maximum of 3000) and external queries are included. Click **Refresh** to view the results.

To focus on a specific subject, enter the subject ID in the input field and click **Refresh**. To focus on a specific site, choose **Site** from the dropdown, enter the site ID or select it from the **...** dialog, and click **Refresh**. A maximum of 3000 subjects can be displayed in Schedule View at one time. To adjust which subjects are displayed, you may specify the starting subject ID or alias, limit (number of subjects to display), and/or order (select for descending, deselect for ascending). Click **Refresh** to view the desired set of subjects.

By default only queries identified for external use are included. Select **include internal queries** and click **Refresh** to view both internal and external queries. If you do not have permission to view internal queries, this option is not available.

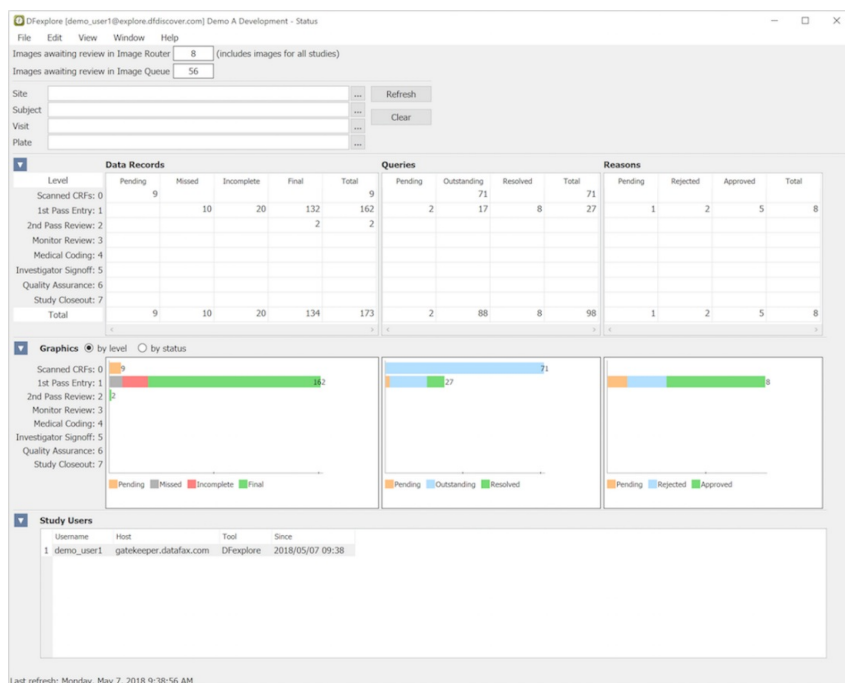
Differences Between Schedule View and DF_QCupdate

Schedule View is quite similar to **DF_QCupdate** in its goals. Both report the visit schedule information for study subjects and identify missing pages and overdue visits. The schedule information presented by both is the same. However, the manner in which the information is generated and maintained differs in several important ways:

1. The results calculated by **DF_QCupdate** are static - they are correct at the time that the report is run and then slowly age until refreshed when **DF_QCupdate** is run again. The results in Schedule View are always up-to-date each time that the Schedule View is presented.
2. To reflect the results calculated by **DF_QCupdate**, missing page and overdue visit queries are maintained in the study database. Schedule View does not create missing page or overdue visit queries.
3. **DF_QCupdate** requires a user with full database permission to run the report, including the permission to add queries. The results are calculated for the entire study every time. Schedule View can be narrowed down to an individual site, or even an individual subject. The Schedule View does not need query write permission and can also be calculated from a read-only database.
4. The output from **DF_QCupdate** is easily shared with external parties, who have no access to the study database, by emailing a PDF generated by **DF_QCreports**. Schedule View requires that the user has access to **DFexplore** and at least read access to their site or subject data. Schedule View reports can also be shared with external parties who have no access to the study database, by emailing the Schedule View reports saved to a file using **File** > **Save as Excel**.

Status View

Status View provides an overview of the status of the study database and shows the list of users who are currently working on the study. It can also be used to quickly assemble a set of records to perform a task by double-clicking any cell in the tables.



Level & Status

The Status View displays the number of data records, queries and reasons in the study database categorized by their workflow level and status. Workflow labels in Status View have been previously defined in **DFsetup**, **[Study] > [Global Settings]**. Each label is followed by the level number that the label represents. If a workflow label is blank and there are no records at this level, the unused level does not appear in the table. If a workflow label is blank and there are records, only the level number appears.

Filtering The Status Report

When Status View is selected it displays the status of the entire study database.

The results displayed in the tables and graphs can be filtered by study site, subject ID, visit and plate. The **[...]** to the right of each entry widget is used to display and select valid entries for each specification. A list of values and ranges can be entered, e.g. Site: 1-9,21,30-44,81,82. Select **[Refresh]** to apply the current filter and **[Clear...]** to remove all filter specifications. After clicking **[Refresh]**, any filter specifications remain in effect for the duration of your login session.

Click **[...]** to the right of **Subject** to open another dialog for [Selecting Subjects based on Criteria](#). This dialog facilitates subject selection based on multiple criteria across multiple plates.

To return to the status for the entire study database select **[Clear...]** and then **[Refresh]**.

Links

You can jump to the records displayed in any cell of the table, including row and column totals, by double-clicking the cell.

Double-clicking a cell in the **Data Records** table creates a task set containing the records defined by the criteria for that cell and opens them in Data View. Double-clicking cells in the **Queries** table allows you to choose to open the task set in either Queries View or Data View, and double-clicking cells in the **Reasons** table allows you to choose to open the task set in either Reasons View or Data View. These task selections are successful only if you have permission to use these views.

User Permissions

The information displayed in Status View depends on user permissions. The tables and graphs include only records you have permission to see, and only the counts shown for records available in the Image Router and the Image Queue are displayed if you have permission to use Image View and Image Router.

Image Queue

Status View displays the number of study CRF pages that have arrived and are waiting to be reviewed and entered into the study database. These records are not counted in the Data table. This count is only visible to users who have permission to use Image View to review and enter these pages. Double-clicking the cell opens Image View for such users.

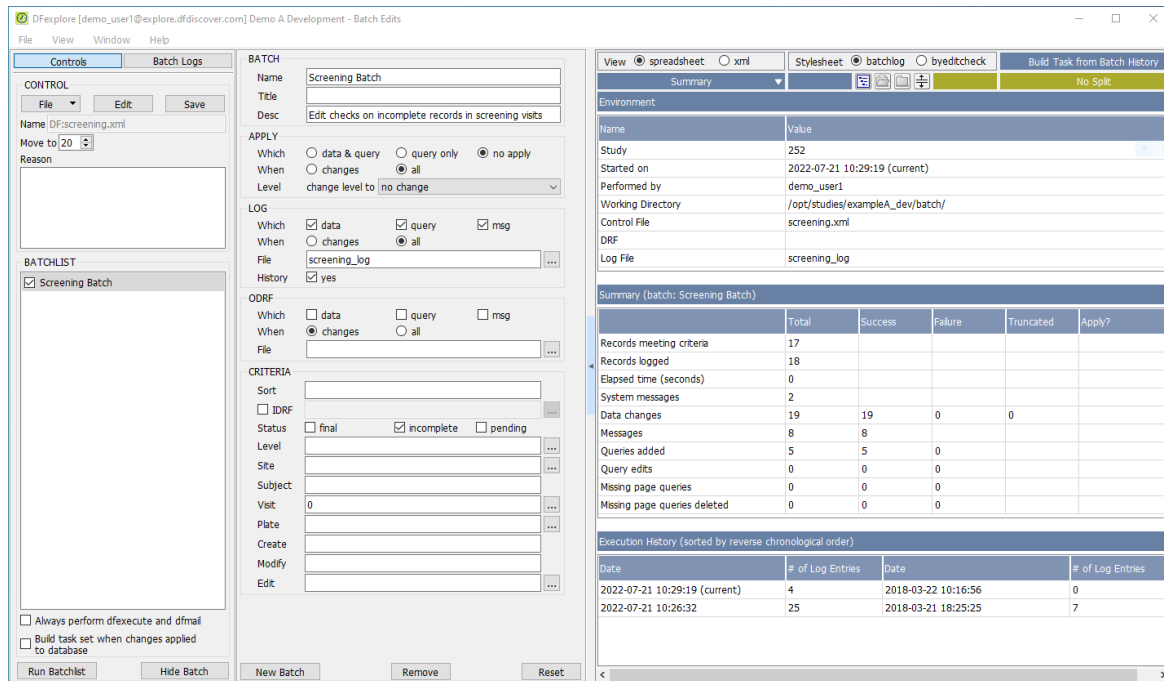
Image Router

Status View also displays the number of CRF pages that have arrived but could not be routed to any of the current **DFdiscover** studies because the study number could not be identified. These pages need to be reviewed manually and routed to the appropriate study if they are study CRFs. This count is only visible to users who have permission to use Image Router. Double-clicking the cell opens Image Router.

Batch Edits View

Edit checks are defined during study setup. They execute interactively during data entry and data review, and can also be programmed to execute unattended, in batch mode.

The Batch Edits View is the interface for controlling this latter, unattended mode.



Batch Edits View provides a visual interface to the **DFbatch** facility described in the [Programmer Guide, Batch Edit Checks](#).

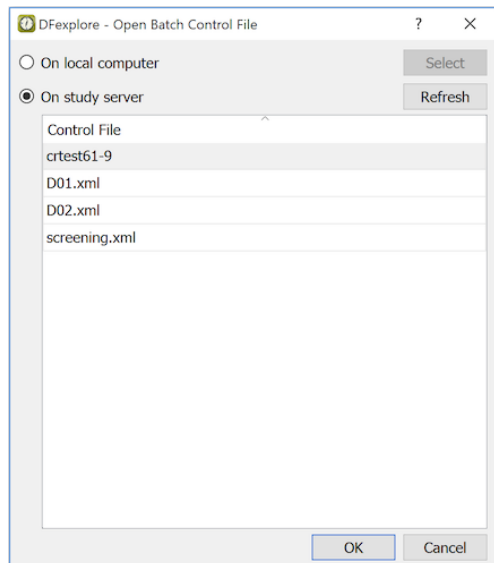
Batch Edits View is divided into 3 separate but related panels:

- **Batch Control:** A batch control file groups together one or more batch definitions. If multiple batch definitions must always execute together, they should all be referenced in the same batch control file.
- **Batch Definition:** A batch definition specifies the records to be included in the batch run and the actions to be applied.
- **Batch Results:** The batch results typically include log messages of the actions taken and their results. There is nothing further for you to specify here.

Batch Control

Click **File** > **New Control File** to start a new batch control file. To open a previously defined batch control file, click **File** > **Open Control File...**

Batch control files can reside on the server (if they are meant to be shared by study personnel), or locally on your computer. Choose the location of the new, or existing, batch control file and click **OK**.



After opening, the batch control file properties are displayed in the **Name**, **Moveto** and **Reason** fields and the names of the batch definitions are displayed in the **BATCHLIST** list.

Two options are offered at the bottom left corner of the dialog.

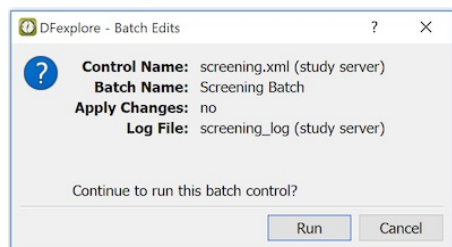
Always perform dfexecute and dfmail: Check this box if you want *dfexecute()* and *dfmail()* to run even though no data changes are applied.

Build task set when changes applied to database: Check this box if you want to build a task set of changes applied to the database.

To review or modify a batch definition before executing it, select it from **BATCHLIST** and click **Show Batch**. The definition of the selected batch updates the second panel, the Batch Definition panel. If the batch was previously executed, the third panel, Batch Results, is also updated to show those previous results.

To execute one or more batches, select them from **BATCHLIST** and click **Run Batchlist**.

Review the information presented in the confirmation dialog. If no changes are needed, click **Run**. If changes are needed, click **Cancel** and update the batch definition and/or selections from **BATCHLIST**.



If the batch is defined to apply data and/or query changes to the database, you will be prompted to confirm this by providing your username and password. If logged in with Microsoft, click **Sign with Microsoft** to authenticate with your Microsoft account to confirm batch execution. Applying changes to the database using batch edit checks cannot be undone.

Batch Definition

The Batch Definition panel is displayed by clicking **Show Batch** in the Batch Control panel.

This panel is a visual editor for a batch definition. A batch definition is divided into a descriptive section (**BATCH**), action sections (**APPLY**, **LOG**, and **ODRF**) and a selection section (**CRITERIA**). Each section corresponds to tags in the batch definition file. These tags and their meaning are explained in [Programmer Guide, Batch Edit Checks](#).

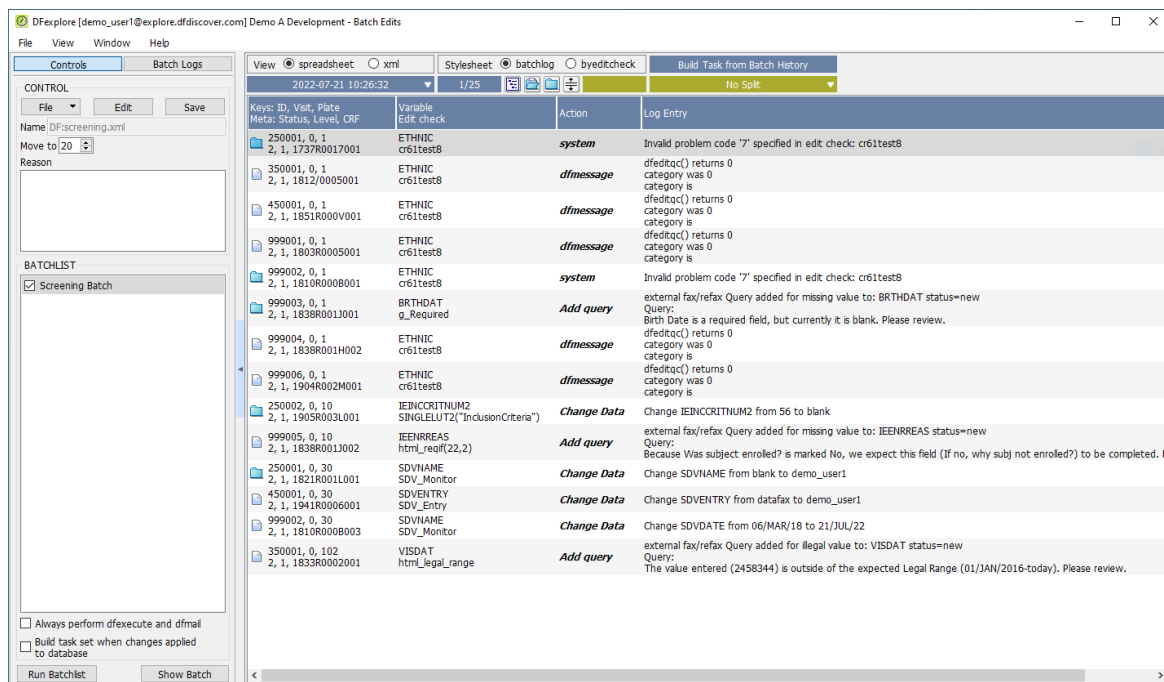
If changes are made to the batch definition, including start a new batch control file, remember to click **Save** to save the changes.

Batch Results

The output from the execution of a batch is presented in the third, Batch Results, panel. The default visualization is an HTML spreadsheet. The underlying XML can also be viewed by choosing **xml**.

There are several options for controlling the presentation of the results.

In the **Execution History** table, the current execution appears first. Double-click one of the rows to view the results for a specific execution.



In this results view, double-clicking any entry takes you directly to the specific record and field in Data View. This allows you to easily navigate between the results of a batch run and the individual records involved.

Image Router

When **DFdiscover** receives pages which it cannot recognize, it stores them in a special folder where they can be reviewed using the Image Router functionality in **DFexplore**. One or more users must be assigned this regular task.

The screenshot shows the DFexplore Image Router interface. On the left, a list of CRF IDs is displayed, with 1815.0008002 selected. The main window shows a detailed view of a 'BLOOD PRESSURE SCREENING VISITS' form. The form includes patient information (Patient Number: 00002, Patient Initials: J A M), screening dates (Screen 1: 05/01/16, Screen 2: 10/01/16), and blood pressure readings (systolic/diastolic mmHg). The form also includes eligibility criteria (Age 10-76 years old, Male or female, not pregnant and using a reliable contraceptive method, Taking blood pressure medication) and a 'Study' dropdown menu. The bottom status bar indicates '7 routable pages (0 busy)' and '1815.0008002 [2550x3300]'.

DFdiscover will fail to recognize pages when there is no barcode (e.g. memos, letters, cover pages), or when the barcode is obscured (e.g. by scanner noise, a coffee stain, something printed over it).

Without a readable barcode, **DFdiscover** cannot automatically identify the study. Thus all unidentified pages are stored in this same special folder. If several studies are running concurrently, the individuals who review and identify pages using the Image Router must be sufficiently familiar with all studies to correctly route each page. Unidentified pages can be received by scan, fax, through **DFsend** or as email attachments.

Study CRFs are not difficult to identify correctly unless the barcode is missing altogether. In such cases the contents and design of the CRF may be enough to correctly identify it. If not, selecting **Page** > **Context** provides information about the sender, which may assist in determining the destination study for the page.

DFdiscover creates missing plate and overdue visit queries for required CRFs and visits that have not arrived (as specified in the study visit map). Thus queries may be generated for pages that have been transmitted by the sites but are currently awaiting identification in the Image Router folder. A recommended procedure is to always ensure that no CRFs are awaiting Image Router identification before **DF_QCupdate** is scheduled to run.

Router Functions

The Image Router is used to:

- Review all unidentified pages.
- Get context (determine when the document arrived and where it came from).
- Delete pages that are not needed (e.g. cover sheets, blank pages).
- Print non-CRF pages or save them to a PDF file.
- Fix any document transmission problems (e.g. flip, rotate, truncate, cut pages).
- Identify CRFs and other subject documents and forward them to the correct study database.

Restrictions

Three factors determine what a user can do in the Image Router:

1. **Router Permission** Permission to use Image Router is typically granted to a small number of users at the **DFdiscover** server site. Users with router permission can start the router and view, print, delete and check the context of all unidentified pages that arrive to the **DFdiscover** server. They can also identify and send pages to any study on the server, even if they have no other study permissions.
2. **Study Status** **DFdiscover** and study administrators can place temporary or permanent restrictions on a study by changing it's status to: disabled, read-only, restricted, or both restricted and read-only. CRFs cannot be sent to studies that are disabled or in read-only mode.

3. **DFdiscover and Study Administrators** Only **DFdiscover** and study administrators can send pages to a restricted study. If a study is also in read-only mode, or is disabled, not even administrators can send pages to the study.

Starting Image Router

To start Image Router, click [Image Router](#) in the study selection dialog. This button is visible only if you have permission to use the Image Router.

Each page, shown in the **CRF ID** page list, is identified by a unique image name (the CRF ID). This image name has the format yyww.ffffppp, where yy is the year, ww is the week, ffff is a sequential document transmission ID, and ppp is the page number within the transmission. Image Router can be used concurrently by multiple users. Pages are locked and released as each user traverses the page list. When a page is selected it, and all other pages in the same document transmission, are locked - this prevents other users from processing pages from the same document.

Small icons reflect the current status of each page in the page list. An exclamation mark signifies a page that is locked by the current user, a lock icon identifies a page that is currently locked by another user, and a red X icon indicates a page that has been processed (routed to a study, deleted, or saved). The user's login name and the **DFdiscover** server name are shown in the title, and a message at the bottom of the screen tracks the number of pages to be routed, the number of pages locked by other users (busy), and the current image name and size in pixels (width x height).

Image Router workflow typically proceeds in three simple steps:

1. select a page,
2. perform image processing (e.g. rotation, flip, etc.) on that page, and
3. identify the "keys" (study, plate and visit) for the page, using the input fields and controls at the bottom of the screen.

For pages that are not study CRFs, it is also possible to print or discard them.

Pages without barcodes may also be identified, provided you are able to determine the study, plate and visit numbers using other features. As an aid to identification the image can be resized from 50-200% using the Zoom option. This has no effect on the size of the image stored in the study database.

If most pages have similar keys the **Preserve keys** check box can be used to prevent the key fields (study, plate and visit) from being cleared after each new page is identified.

If a set of pages all have the same keys and do not require image processing, they can be identified together in one step by making multiple selections from the page list before clicking [Identify](#).

Image Router sends all identified pages to the new record queue for the respective study where they join other pages that were identified automatically from their barcodes.

File Menu

Use the **File** menu to access generic Image Router functions. Remember that Image Router is a sub-window of **DFExplore**. You can move to and from **DFExplore** using menu items from the **File** menu.

Refresh

Select [Refresh](#) to refresh the page list with any unidentified pages that may have arrived since the current session began. Image Router does not automatically update the list of CRF IDs in the page list.

New Study

Select [New Study](#) to open the study selection dialog and select a study for concurrent access in another instance of **DFExplore**, while keeping the Image Router window active.

Close Image Router

Select [Close Image Router](#) to close the Image Router window and return to the **DFExplore** login dialog.

Page Menu

This menu accesses the functions that allow you to manipulate pages (rotate, shift, flip, cut, truncate, and reset) before sending them to the study database.

For **DFdiscover** to properly identify and read a CRF, the signature line (horizontal line at the top of the CRF) first has to be located and placed in a standard, expected position. Without this standard positioning, **DFdiscover** will have difficulty locating, and reading, the data fields positioned on the remainder of the CRF. Under normal circumstances, **DFdiscover** does all of this automatically. For CRFs that cannot be automatically identified, user intervention using the functions in this menu is needed.

This menu also contains functions for navigating to other pages, printing pages and determining where each page came from (context).

Rotate

Select [Rotate](#) to correct page rotation. This is needed if the page signature line at the top of a study CRF is not horizontal. Page rotation usually results from failure, at the transmitting site, to adjust the page guides snugly against the sides of the CRF pages when they are being scanned.

Instructions for this operation appear in the status line at the bottom of Image Router window. Click the left mousebutton on the top-left end of the horizontal signature line and then click again on the top-right end of this line (or click the right mousebutton to cancel this operation). When the operation is complete, the screen updates to show the realigned image. Click [Reset Image](#) to undo this operation, and try again.

Shift

Use **Shift** when the page does not need to be rotated, but instead only needs to be shifted vertically. Shift is used to register the upper-left corner of the page signature line.

To shift a page click the left mousebutton anywhere on the top edge of the horizontal signature line (or click the right mousebutton to cancel this operation). The vertical location of the mouse pointer is important - the horizontal position is ignored. After clicking the left mousebutton once, the screen updates with the shifted image. Click **Reset Image** to undo the shift and try again.

Flip

Selecting **Flip** turns the page upside down, by rotating it 180°. Selecting it a second time returns the page to its original position.

Cut

Occasionally a page may be received that is really 2 pages (or more) joined together. This can occur if the transmitting scanner is slipping while pulling consecutive pages through the document feeder. In the Image Router window this is evident because the page length is much greater than the length of a single page. In such cases, it is necessary to cut the long page into individual pages at the appropriate page boundaries.

WARNING: The Cut action cannot be undone.

Selecting **Cut** overlays a horizontal line on the page. Move this line to the desired cut position (representing the bottom of the first page) and click the left mousebutton to register the cut point, or click the right mousebutton to cancel.

After the cut point is registered a confirmation dialog appears. A page cut operation cannot be reversed. Click **OK** to confirm the page cut or **Cancel** to abort the action.

On rare circumstances, the original page may contain more than 2 consecutive pages. In this case, simply select the second page (the bottom portion of the original page) and repeat this procedure to cut again (and maybe again).

Truncate Length

The size of the page (width x length, in pixels) is shown in square brackets at the bottom of the screen. After a CRF has been shifted to the top of the page signature line it should not be longer than 1050 pixels in standard definition (approximately 1120 pixels if the source document was A4 size), or 3150 pixels in high definition. Any other length suggests that there are either multiple concatenated pages (in which case the page should be cut) or there is "noise" (unneeded content) at the end of the page. In such cases, examine the bottom of the page to see if it contains noise. If it does, select **Truncate Length** to remove the excess length.

Click **Reset Image** to undo the **Truncate Length** operation and restore the original page length.

Trim Width

Scanners or fax machines that can accommodate pages wider than 8.5 inches require their paper guides set to 8.5 inches for proper scanning of letter-size pages into **DFdiscover**. If the guides are set too wide, the paper can tilt or shift, resulting in skewed or abnormally wide images. When pages like this are received, they generally appear in the router because they are wider than the width of a US letter-size page. To route a wide page, trim the width of a page by selecting **Trim Width**. Two dashed vertical lines appear over the document spaced 8.5 inches apart. Using the mouse, position the lines over the area of the page to preserve. Click the left mousebutton to keep the area between the lines, and discard the page area that lies outside these two lines, or click the right mousebutton to cancel the operation. Click **Reset Image** to undo the **Trim Width** operation.

Rotate 90° CW/CCW

To rotate a page 90° clockwise select **Rotate 90° CW**, or counter-clockwise by selecting **Rotate 90° CCW**. Each time the option is selected, the current page is rotated 90° in the specified direction. This is useful when a sender sends a page in landscape orientation and it needs to be put into portrait orientation. Click **Reset Image** to undo all operations on the page, or rotate the page in the opposite direction to return it to its previous orientation.

Rotate 90° CW/CCW and scale

It is possible to process landscape pages by rotating them into portrait orientation and scaling them to fit the width of a portrait page. This is performed using **Rotate 90° CW and scale** or **Rotate 90° CCW and scale**. Select the appropriate menu item to apply the needed rotation. The page is rotated and then scaled to fit the width of a portrait US letter page.

Print

To print one or more pages, highlight the page or pages from the page list and select **Print**. The operating system print dialog is displayed. Change the necessary print settings before printing.

Export as PDF

To export one or more pages in a PDF file, highlight the page or pages from the page list, and select **Export as PDF**. The operating system's standard file save dialog is displayed. Specify a file name and save.

Previous

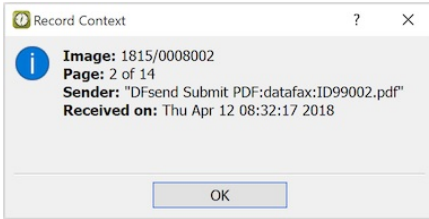
Move to the previous page in the Image Router window.

Next

Move to the next page in the Image Router window.

Context

This function provides information that may aid in determining the source of an unidentified page. It provides the page number within the document, the date and time on which the document was received, and the sender identification header - which is usually the sender's an email address, fax number, or username from a **DFsend** user.



Reset

Select this function, or **Reset Image**, to undo all Rotate, Scale, Shift, Flip, Trim and Truncate manipulations that have been applied to the current page; the only exception is Cut, which cannot be undone. Reset is also performed automatically when a different page is selected before identifying the current one to send it to the desired study database. Once a page has been identified, page manipulations are permanent.

Action Menu

This menu contains all of the functions that routes pages to a study and remove pages from the Image Router. All actions are immediate. Once committed they cannot be undone.

Rotate/Shift/Identify

Most CRF pages can be aligned, identified and routed to the appropriate study database in a single step by selecting **Rotate/Shift/Identify**. Follow the directions at the bottom of the window to identify the CRF page signature line. The page is then rotated and shifted (if necessary) and another attempt is made to read the barcode. When this has been done, enter or correct the keys (Study, Plate and Visit) as needed and click **Identify**.

If the plate is defined as having the visit number in the barcode it must be entered before clicking **Identify**; an error message appears otherwise. Alternatively, when the visit number is the first data field on the plate, the Visit key should be left blank - it is silently ignored if a value is entered.

A Right-Click mousebutton aborts the Rotate/Shift/Identify action. Once **Identify** is selected, the action is committed and cannot be undone. The page is sent for ICR processing and routed to the designated study database. There is a brief pause while this is being done. Then the page is removed from the page list, and the next unidentified page is displayed (if there is one).

Move

Select **Move** to move a page to a specified file name on the local computer. Specify the destination location for the file using the operating system's standard file dialog. Moved files are removed from the **DFdiscover** server and stored in PNG format on the local computer. This may be appropriate for documents of a personal, or non-study, nature.

Discard

To discard an image, highlight the image in the page list, and select **Discard**. This action cannot be undone and requires a confirmation dialog before proceeding.

To discard multiple pages, highlight the desired pages from the page list before selecting **Discard**.

User Settings

User Profile, Change Password

When the **DFdiscover** administrator created your account, they defined a user profile for you. That profile includes your name, your mailing address, your contact information and your password.

You can examine your current user profile by choosing **File** > **User Profile...**.

DFExplore - User Profile

Username: demo

Full Name: Demo Account

Email: demo@dfnetresearch.com

Change Password...

Affiliation: DFnet

Address: 140 Lakeside Ave. Suite 310

City: Seattle Postal Code: 98122

State: Washington

Country: USA

Telephone: 1-206-322-5931

Fax:

Local time (UTC-05:00) is displayed for data, queries, and reasons in the Data, Image, Queries, and Reasons Views. Server time (UTC-05:00) is displayed in all other Views and in the Page and Field History of Changes in Data and Image Views.

OK

Values below the horizontal rule can be edited. It is not possible to change your **Username**, **Full Name**, or **Email**. Edited values are saved when clicking **OK**.

NOTE: The **DFdiscover** administrator can centrally update the **Full Name** or **Email** if necessary.

You can change your password at any time by clicking **Change Password...**. The dialog requires you to enter a new password and then re-type it to confirm the changed password.

DFExplore - Change Password

Your password has expired, or has never been initialized.
Choose a new password.

New Password:

Confirm Password:

OK Cancel

If you logged in with a Microsoft login, the change password button will not be shown in the User Profile dialog.

The User Profile dialog also displays details about the time zone in UTC (Coordinated Universal Time) used for timestamps shown in DFExplore, including the local time zone detected on your device. The accuracy of these time zones is dependent on your local device time being correct.

Session Settings

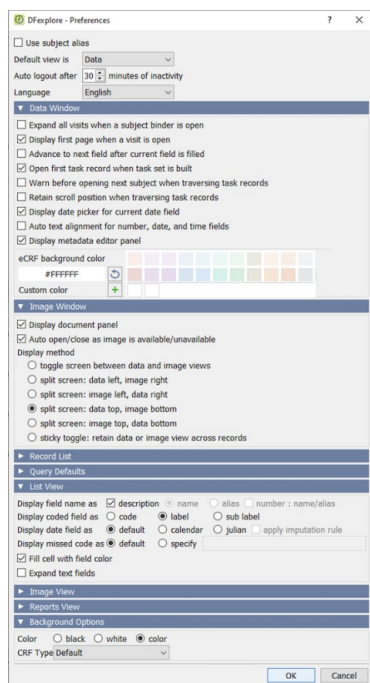
DFExplore saves several attributes of your current session so that those attributes can be automatically applied when you login again. Session settings are unique to a specific username, **DFdiscover** server and study. Further they are stored on the local computer. This combined flexibility allows you to have different settings for different studies, different servers and different local computers.

The session attributes that are saved include:

- Window layout, window size and dialog positions
- Preferences
- Proxy configuration settings

User Preferences

The appearance and behavior of many features and dialogs within **DFExplore** can be customized with application preferences. Select **File** > **Preferences** to access these preferences.



Preferences are user and study specific. Changes are applied immediately and are preserved across sessions. Some preferences may refer to parts of **DFExplore** for which you do not have permission, and will thus be irrelevant. Some preferences may be pre-set and/or locked by the study coordinating center, so you may not be able to change them.

A description of each of the preference settings follows.

General

- **Use subject alias** By default, the numeric subject identifier is displayed. If subject alias is defined at the study setup level, enable this setting to use the subject alias in place of the numeric id.

NOTE: If subject aliases are used for a study, all subject IDs should be included in the subject alias map, even if the alias is the same as the subject ID. If no alias has been defined for a subject ID but the subject alias setting is enabled, search options and report filters will not find the subject in **DFExplore**.

- **Default view is:** There are several views in **DFExplore**. From the drop-down list, choose the view that you would like to open by default each time you start **DFExplore**.
- **Auto logout after XX minutes of inactivity:** An automatic timeout, after a period of inactivity, is required to meet regulatory requirements and protect subject confidentiality. Study administrators specify a default and maximum time period for each study. You can change this default to any value up to the maximum.
- **Language:** **DFExplore** supports multi-language studies and displays eCRFs in the selected language where translations have been defined. If your study includes translated eCRFs, the dropdown will provide the list of available languages. Note that this setting only applies to the eCRFs in this study, not to the **DFExplore** application interface.

Data Window

The data window is visible in Image View as well as Data View.

- **Expand all visits when a subject binder is open:** If this preference is checked all visits are also opened to show the CRF pages they contain. Otherwise, subject binders open to show all study visits but all visits are closed.
- **Display first page when a visit is open:** If this preference is checked, the data screen is automatically loaded with the first page of the visit when a new visit is opened.
- **Advance to next field after current field is filled:** By default, the focus remains on each field until you press the **Tab** or **Return** to advance to the next data field. Enable this preference to automatically advance to the next data field when the response for the current field is filled.
- **Open first task record when task set is built:** If this preference is selected the first data record is opened automatically when a new task is selected; otherwise, you must open the first task record manually by selecting the desired subject binder.
- **Warn before opening next subject when traversing task records:** This preference is relevant if you have access to record selection tasks and is used to ensure that you are aware of transitions from records for one subject to records for a different subject.
- **Retain scroll position when traversing task records:** This preference is relevant to users who have access to record selection tasks. It is useful when the task involves a review a fields near the middle or bottom of each page, as it prevents the normal scroll to the top of each new page.
- **Display date picker for current date field:** For fields that require a date value, enabling this preference displays a calendar widget next to the field when it gets the focus. Date values can be entered by selecting them from the calendar widget or via normal data entry.
- **Auto text alignment for number, date and time fields:** The font used for data entry may not exactly fill the space available in the data entry field. Checking

this preference causes the data value to re-draw after entry so that it "fills" the data entry field. This is purely a visual preference and has no impact on the data values.

- **Display metadata editor panel:** The metadata editor panel is an optional view of the Query, Reason, Metadata and Help windows. Enabling this preference displays the metadata editor panel and hides the separate Query, Reason and Metadata panels, expanding the subject binder list.
- **eCRF background color:** For an eCRF data entry page, choose the color pair that is used to background fill the alternating rows of data entry fields. Commonly used color pairs are presented or you can specify a custom color.

Image Window

The image window is visible in Image View as well as Data View.

- **Display document panel:** The document panel is a convenience interface, expediting the [Attach Subject Document](#) action when many documents require uploading. Enabling this preference displays the document panel as part of the image window. The document panel can also be detached from the image window and positioned independently.

The document panel lists each previously attached document by name and with a green checkmark. The document panel also includes a drag-drop area where documents from the local computer can be attached. Such documents that have been attached and not yet saved are shown with an empty square. Before saving, such documents can also be deleted by highlighting the row and clicking the red 'X'. If there are enough documents listed that the drag-drop area is not visible, new documents can be dropped on any part of the panel.



- **Auto open/close as image is available/unavailable:** If checked, images/documents are automatically displayed when a page having such images is selected. When this preference is selected the presentation of the data and image window is further refined by the **Display method** choice:
 - **toggle screen between data and image views:** Switching between data and image views is performed using the blue image button in the bottom-right corner of the screen, but the data view will always appear on switching to a new page in the subject binder.
 - **split screen: data left, image right:** If an image is attached to the current data record, split the screen horizontally and display the data window to the left and the image window to the right.
 - **split screen: image left, data right:** If an image is attached to the current data record, split the screen horizontally and display the image window to the left and the data window to the right.
 - **split screen: data top, image bottom:** If an image is attached to the current data record, split the screen vertically and display the data window on the top and the image window on the bottom.
 - **split screen: image top, data bottom:** If an image is attached to the current data record, split the screen vertically and display the image window on the top and the data window on the bottom.
 - **sticky toggle: retain data or image view across records:** Switching between data and image views is performed using the blue image button in the bottom-right corner of the screen, and the last setting remains in effect when switching to a new page in the subject binder.

Record List

The Record List appears to the left of the main window. It's primary purpose is to aid navigation of sites, subjects, visits and plates.

- **Display visit as number:label, number, label:** Each subject visit has both a number and a descriptive label. This preference determines how a visit is identified when a subject binder is opened.
- **Display plate as number:label, number, label:** Each plate has both a number and a descriptive label. This preference determines how the pages within subject visits are identified when a visit is opened.
- **Display site as number:label, number, label:** Each site has both a number and a descriptive label. This preference determines how sites appear in the record list.
- **Record navigation:** This preference determines whether the contents of the list will be displayed as nested sites, subjects, visits, and plates, or as a linear list.

Query Defaults

- **Use external or internal:** This preference is relevant to users who are allowed to create new queries and determines the default usage type in the query creation dialog. External queries are directed to clinical sites, while internal queries are not.
- **Type clarification or correction:** This preference is relevant to users who are allowed to create new queries and determines the default response type in the query creation dialog. Clarification queries are used to request a reply to a question, while correction queries are used to request a correction to one or more data fields.

List View

- **Display field name as description, name or alias, and optionally prepended with the field number:** Specify column labels for the list view data table. These labels can display the field description, field name or field alias, and may optionally include the field's data entry tab order number.
- **Display coded field as code, label, or sub label:** For fields that have codes and labels and, optionally, sub labels, e.g. 1=male=M, 2=female=F, this preference determines whether the code, label, or sub label is displayed in List View. If no sub label is defined for a field, the label is displayed instead.
- **Display date field as default, calendar, julian, and apply imputation rule:** Dates may be shown exactly as entered into the study database (default), in calendar format (with 4 digit years), or as a julian number. In addition any imputation rules that have been specified for partial dates may be applied if the calendar or julian format is selected.
- **Fill cell with field color:** Each cell in the data table can be presented with the same color used in Data View and Image View.
- **Expand text fields:** If cells in the data table are too small to display the entire data field, enabling this preference expands the cell when it has the focus so that it can display all of its contents.

Image View

When a CRF page is re-submitted users perform duplicate resolution by loading the existing data record, comparing it with the new image, and correcting any data fields that need to be updated. During this process users can select the image count button at the bottom of the screen to review the previous and new CRF images. Alternatively either or both of the following preferences can be used to display the image review dialog automatically:

- **When the existing record is loaded:** Check this option if you want to compare the old and new CRF images before reviewing and correcting any data fields.
- **When the revised record is saved:** Check this option if you want to delay image comparison until after reviewing, correcting and saving the data record.

Reports View

- **Each report run opens in a new tab:** Check this option to have the output from each report run, or explain, appear in a new tab. If this option is not checked, the output from each report run, or explain, appears in the same tab, overwriting any previous output

Background Options

- **Color black, white or color:** Are data fields displayed on a black, white or color background? Color is useful if color CRFs have been imported in DFsetup to create the data screen backgrounds.
- **CRF Type:** Different versions of some or all of the CRF pages can be imported during study setup. This preference allows you to select the version of the CRFs to be used for both the data entry screens and when printing CRFs or creating PDFs.

Appendix

Terminology

This section explains some of the terminology used in this guide.

CDISC	CDISC is a global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. CDISC standards are vendor-neutral, platform-independent and freely available via CDISC .
Electronic Signature	Your electronic signature has two parts: your login name and your password. You must specify both parts when you login to the study's DFdiscover server, either using your DFdiscover credentials or with your Microsoft account linked to your DFdiscover login name, if allowed on the server. When executing your electronic signature, you will be required to re-authenticate using the same account credentials that you used to log in (DFdiscover or Microsoft). All data collected is recorded under your login name and can be traced in DFdiscover audit trail reports, available in Page History.

Final	Final is a record status. A page can be saved with status Final if there are no illegal values or unanswered queries from the study coordinating site. DFexplore marks Final pages with a green shaded rectangle (see also Incomplete and Pending).
Incomplete	Incomplete is a record status. A page can be saved with status Incomplete if it has one or more fields which are incomplete or illegal, or outstanding queries. DFexplore marks Incomplete pages with a red partially shaded rectangle (see also Final and Pending).
ODM	The CDISC Operational Data Model (ODM), which is maintained by the CDISC XML Technologies Team, is designed to facilitate the regulatory-compliant acquisition, archive and interchange of metadata and data for clinical research studies. ODM is a vendor neutral, platform-independent format for interchange and archive of clinical study data. The model includes the clinical data along with its associated metadata, administrative data, reference data and audit information. All of the information that needs to be shared among different software systems during the study setup, operation, analysis, submission or for long-term retention as part of an archive is included in the model.
Page or Plate	<p>Page and plate are 2 terms used interchangeably to refer to a logical grouping of data items (aka data fields) presented with a layout determined by the study sponsor, to fit on a single sheet of paper, or single screen. Each page may stand alone, or pages may be grouped into multi-page forms. A collection of pages (or forms) constitute a visit, and a collection of visits constitute the subject binder which holds all study data for an individual subject.</p> <p>In a paper-based approach to data collection, these pages are printed, completed and sent to the DFdiscover system. When using an EDC approach, the same pages are completed using DFexplore.</p>
Pending	<p>Pending is a record status. During new data entry a page can be saved with status Pending to indicate that you are not finished with it and plan to return to it shortly. These pages are saved at workflow level 0 and do not move to higher levels until they are saved with status Final or Incomplete. Typically pending pages at level 0 will not be reviewed by the study coordinating site until they progress to level 1 or higher.</p> <p>Pages which have progressed beyond level 0 cannot return to level 0, but they can be reset to status Pending to indicate that there is something incorrect which needs to be corrected before the data can be used in statistical reports. The ability to demote records this way is restricted to users with Data View - with Select permission. DFexplore marks Pending pages with an orange outline rectangle (see also Final and Incomplete).</p>
Query	A query is a question or comment about a data value. The study coordinating site may add a query to any data field to request a correction or clarification. DFexplore colors fields with an outstanding query blue. When a reply is provided to a query, or a reason is added to explain the field, the color changes 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 explaining a data value can be added to any data field. This is particularly useful as a way of explaining unusual values and thereby avoiding a data query from the study coordinating site. DFexplore 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 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 you make to a page are saved to the study DFdiscover server until you click one of the 3 Save buttons: Final, Incomplete, or Pending. If you leave the computer without saving your work, DFexplore will time-out after a few minutes and the changes you made will be lost. However, you will be warned that this has happened the next time you connect to the study and you can opt to return to the same page.
Subject	An individual participating in a research project for whom data will be collected is a subject. 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 DFexplore , subject binders are displayed in a list by subject ID, with an associated icon that shows whether the binder is empty or contains recorded data, and whether that data is currently complete, incomplete or pending.

Keyboard Shortcuts

This section is a reference for the standard keyboard shortcut keys available in the Windows **DFexplore** client. Keyboard shortcuts for the macOS **DFexplore** client are the same except that the Ctrl key is replaced with the Command key.

Switching Views

Ctrl+1	Switch to Dashboard View
Ctrl+I	Switch to Image View
Ctrl+D	Switch to Data View
Ctrl+U	Switch to Queries View
Ctrl+R	Switch to Reasons View
Ctrl+E	Switch to Reports View
Ctrl+Shift+S	Switch to Schedule View
Ctrl+S	Switch to Status View
Ctrl+L	Switch to List View
Ctrl+Shift+B	Switch to Batch Edits View

Data Entry Field Traversal (Data, Image Views)

Tab, Return	Move focus to the next field
Shift+Tab, Shift+Return	Move focus to the previous field
Ctrl+Tab, Ctrl+Return	Move focus to the next problem field
Ctrl+Shift+Tab, Ctrl+Shift+Return	Move focus to the previous problem field

Missing Value Code Assignment (Data, Image Views)

Ctrl+M	Repeat assignment of the same missing value code
--------	--

Scrolling an Image (Data, Image, List Views)

Ctrl+T	Scroll to the top of the image
Ctrl+B	Scroll to the bottom of the image

Table Zooming Contents of a Report

Ctrl++	Zoom in
Ctrl+-	Zoom out
Ctrl+0	Reset zoom

Open a New Study (File-New Study menu)

Ctrl+N	Invoke the DFexplore login dialog to
	open a new study

Editing Text

Ctrl+Z	Undo
Ctrl+Y	Redo
Ctrl+X	Cut
Ctrl+C	Copy
Ctrl+V	Paste
Ctrl+A	Select All

Common Error and Warning Messages

This section details some messages that users may encounter during their use of **DFexplore**.

DFexplore Login

Message:	The DFdiscover server is not reachable. Confirm the server name and network connection.
Possible Cause:	There is no internet connection available or the server address/name entered is invalid.
Solution:	Confirm that your internet service is functioning properly. Confirm that you have correctly entered the DFdiscover Server in the login dialog. Otherwise, contact your Study Coordinator or DFdiscover Administrator.
Message:	Unable to connect to the DFdiscover server. Confirm that DFdiscover is available.
Possible Cause:	DFdiscover is not running on the specified server.
Solution:	Contact your Study Coordinator or DFdiscover Administrator and confirm that the DFdiscover server is available and running properly.
Message:	Unable to get a list of studies from the server.
Possible Cause:	The user has not been given access to any studies or the DFdiscover server is not running.
Solution:	Contact your Study Coordinator or DFdiscover Administrator.
Message:	Error: Unable to load study setup file
Possible Cause:	The study Setup file does not exist or is empty.
Solution:	Contact your Study Coordinator or DFdiscover Administrator.
Message:	Unable to load subjects.
Possible Cause:	The sites database does not exist or is empty, or you do not have permission to access subject IDs due to restrictions defined by the Study Coordinator or DFdiscover administrator.
Solution:	Contact the Study Coordinator or DFdiscover Administrator.
Message:	Unable to load visits.
Possible Cause:	The DFdiscover study DFvisit_map does not exist or is empty, or the user may not have permissions to access the necessary visits and/or plates due to restrictions defined in their study role.
Solution:	Contact the Study Coordinator or DFdiscover Administrator.
Message:	It appears that the local computer's date and time are incorrect. DFexplore has been set to view only mode until the date and time are fixed, and then login again.
Possible Cause:	Either DFexplore cannot obtain a valid date and time from the local computer, or the value obtained is more than 48 hours ahead or behind the value obtained from the study database server.
Solution:	Update the date and/or time on the local computer.

Data Entry

Message:	Due to inactivity, the connection has been logged out.
Possible Cause:	Your DFexplore session has been inactive for the number of minutes specified by the Auto Logout setting.
Solution:	You can customize the number of minutes after which the DFexplore auto logout takes effect. The default Auto Logout setting may be changed by logging into DFexplore , selecting File > Preferences and changing the Auto Logout preference.
Message:	The definition of this page has changed. This page needs to be reviewed centrally before you can access it again. Please notify your study coordinator.
Possible Cause:	This message arises when the number of fields on a page has been changed so that its definition no longer matches the data already existing in the database.
Solution:	The data records for the page will need to be reformatted before you can access them. Contact your Study Coordinator or DFdiscover Administrator.
Message:	This page cannot be saved with status Final because of problems identified by edit checks.
Possible Cause:	Edit checks that are set to execute upon saving the page may cause certain data fields to be marked with an outstanding query or an illegal data value. If either or both exist, it will not be possible to save the page with status Final.
Solution:	Review the page for any outstanding queries (blue fields) and/or illegal data values (red fields). Correct those problems or save the page using Pending or Incomplete status.
Message:	Error in saving record changes. Cause: A valid date/time stamp could not be created.
Possible Cause:	DFexplore cannot obtain a valid date and time from the local computer, or the value obtained is more than 48 hours ahead or behind the value obtained from the study database server.
Solution:	Update the date and/or time on the local computer.
Message:	Field field_name: storing value field_value (which contains illegal/extra characters) into variable has altered the value.
Possible Cause:	The field value stored in the study database is different from the value displayed in the field widget on screen. The database value may not match the field format, or may be larger than the current field store length. The study setup specifications may have been changed to make previously entered values incompatible with the current field specifications.
Solution:	Re-enter the specified fields with values compatible with the current field properties and save the record to the study database.

Programs

This section describes the standard **DFdiscover** programs available for both adhoc record selection and task definition.

DFmkrdf.jnl - make **DFdiscover** DRF file from study journals

Program DFmkrdf.jnl processes the study journal files and can be used to identify records entered by specified users during specified times with specified criteria. Its output includes all records that match the specified criteria, but any given user will only see those records they have permission to get. The program usage message follows.

DFmkrdf.jnl - make or load a DFdiscover Retrieval File

```

USAGE: DFmkrdf.jnl [ DFNUM ] [-t date1-date2 | -days #]
      [-u include_users] [-xu exclude_users]
      [-v levels] [-s statuses] [-l IDs] [-S SEQs] [-P plates]
      [-image yes|no] [-d 1|2] [-cv levels] [-cs statuses]
      [-records #] [-cases #] [-put drfname] [-h header]
      [-get drfname] [-test]

OPTIONS:
DFNUM      ... DFdiscover study number may be 1st argument or set in
-t yymmdd-yymmdd ... selection period: dates during which records were saved
-days #    ... select records saved in the past # days
-u list of users ... select records saved by specified users
-xu list of users ... exclude records saved by specified users
-v # # #   ... select records saved at specified validation levels (0-7)
-s status  ... select statuses: final,incomplete,pending,missed
-l # # #   ... select subject IDs
-S # # #   ... select visit numbers
-P # # #   ... select plate numbers
-image yes|no ... select records with images only, or without images only
-d 1       ... deselect if criteria no longer apply at end of selection period
-d 2       ... deselect if criteria no longer apply now (journal's end)
-cv # # #  ... deselect records not currently at specified validation levels (0-7)
-cs status ... deselect records not currently at the specified statuses

```

-records # ... maximum number of data records to be included in the drf file
 -cases # ... maximum number of subjects to be included in the drf file
 -put drfname ... write output to a specified drf file in the study drf folder
 -h header ... include a descriptive header/title for the drf file
 -get drfname ... load an existing drf file from the study drf folder
 -test ... check and display record selection options then quit

NOTES:

1. DFNUM does not need to be specified when running DFmkdrf.jnl in DFExplore; or if environment variable DFNUM is set to the study number when running shell scripts.
2. Input: DFmkdrf.jnl reads the study journal files and thus will not generate correct output if any of the journals have been removed or truncated.
3. Output: a DRF record is created for journal records that meet all selection options at some point in the specified time period:
 - a) -d 0: even if these records no longer meet the selection options (default), or
 - b) -d 1: if they still meet the selection options at the end of the time period, or
 - c) -d 2: if they still meet the selection options now.
4. A DRF record is not created for any record deleted after meeting the selection criteria because a deleted record cannot be retrieved from the study database.
5. If the keys (ID,Visit,Plate) are changed after a record meets the selection criteria, a DRF record will be created for both the old keys and the new keys if they both correspond to a current data record.
6. The record selection period may be specified using:
 yymmdd-yymmdd or yymmdd-today ... a date range, or
 yymmdd or today ... a single date
7. If the -drf option is not specified output is written to standard out.
8. If the -cases and -records options are both specified, -cases has priority
9. When running DFmkdrf.ec from the command line, you need to set the following environment variables: DFSERVER, DFUSER, DFPASSWD and DFNUM to the values you would use if you were logging into DFExplore via the login dialog. DFNUM can also be passed as the first argument to DFmkdrf.jnl on the command line as shown in the examples below.

EXAMPLES:

Output DRF records for data records in study 253 that were saved with associated images by jack or dianne at level 1 in Nov. 2017, regardless of whether these records were subsequently saved by someone else or at different levels or without an associated image.

```
DFmkdrf.jnl 253 -image yes -u jack,dianne -v 1 -t 171101-171130
```

Repeat the above but only create DRF records if the selection criteria remain in effect now, i.e. deselect any records that no longer meet the selection criteria at the end of the audit trail.

```
DFmkdrf.jnl 253 -image yes -u jack,dianne -v 1 -t 171101-171130 -d 2
```

Get records saved at level 3 by jack which are currently back at level 1

```
DFmkdrf.jnl 253 -u jack -v 3 -cv 1
```

Create a DRF file named myTest.drf for data records in study 253 which were saved in the past 10 days with visit numbers 1,2 or 50-59 and record status = incomplete by someone other than the current user.

```
DFmkdrf.jnl 253 -days 10 -S 1,2,50-59 -s incomplete -xu whoami -put myTest.drf
```

Load DFUnexpected.drf, a DRF file created by DF_QCupdate and stored in the study drf folder.

```
DFmkdrf.jnl 253 -get DFUnexpected.drf
```

DFmkdrf.ec - make DRF file from edit checks

Program DFmkdrf.ec creates a DFbatch file and runs it to identify records with edit checks that would display a message, create or edit a query or modify data field were they to be run interactively. No changes are made to data or metadata. The output is a data retrieval file listing the records that met the specified criteria. Any given user will only see those records they have permission to get. The program usage message follows.

DFmkdrf.ec - make DRF records by running DFbatch to execute specified edit checks

USAGE: DFmkdrf.ec [DFNUM] -P plates -E editchecks [-v levels -s statuses -I IDs -S SEQs]
 [-P another batch specification] [-which] [-warn] [-L level]

OPTIONS:

DFNUM ... DFdiscover study number
 -P Plates ... plate specification starts each new batch specification
 -E Edit checks ... edit check names to be executed on the specified plates
 -v # # # ... select records by specified validation levels (0-7)
 -s status ... select records by record status final,incomplete,pending,missed
 -I # # # ... select records by subject IDs
 -S # # # ... select records by visit numbers
 -L # ... apply level (0~7, default 0)
 -which msg qc data ... determines EC events that trigger creation of a DRF record
 -warn ... display any warning messages generated by DFbatch
 -u ... print this usage message and quit

NOTES:

1. DFExplore uses environment variable DFNUM which is set to the current study number. Only specify DFNUM on the command line when running DFmkdrf.ec from a shell script or terminal session where DFNUM is not set.
2. Each batch specification must begin with the -P and -E options, in that order.
3. Use -E ALL or -E all to include all edit checks on the specified plates.
4. The -which option determines the conditions under which a DRF record is created. Edit checks are executed with APPLY=none so no changes are made to the database. Instead a DRF record is created for the current page if the edit check would do the following with APPLY turned on:
msg - execute a message function: dferror, dfwarning, dfmessage
qc - create a new query or edit an existing one
data - modify a data field
The default value for the -which option is msg qc data, i.e. all 3 triggers apply.
5. The -which option applies to all batches. Only 1 -which option can be specified.
6. Temporary files are created in the study work directory and then removed.
7. User permissions are applied.
8. When running DFmkdrf.ec from the command line, you need to set the following environment variables: DFSERVER, DFUSER and DFPASSWD to the values you would use if you were logging into DFExplore via the login dialog.
9. The -L option is required for users with limited write level permissions. Without this option specified, specified edit checks run for users with write level 0 permissions only.

EXAMPLES:

Write DRF records to standard out for study 253 if edit check test1 or test2 on plates 1-3 would display a message, add or modify a query or make any changes to a data field.
DFmkdrf.ec 253 -P 1-3 -E test1,test2

Same as the first example but only trigger these edit checks on plate 1 and only for data records that have status final and are at validation levels 3-6.
DFmkdrf.ec 253 -P 1 -E test1,test2 -s final -v 3-6

Same as previous example but trigger test1 on all plate 1 records and test2 on plate 2-3 records that have status final and are at validation levels 3-6.
DFmkdrf.ec 253 -P 1 -E test1 -P 2-3 -E test2 -s final -v 3-6

Same as the previous example but edit checks test1 and test2 only generate a DRF record if they would have created a new query or modified an existing query.
DFmkdrf.ec 253 -P 1 -E test1 -P 2-3 -E test2 -s final -v 3-6 -which qc

Create DRF records for any edit check that would change a data field.
DFmkdrf.ec 253 -P 1-499 -E ALL -which data

Selecting Subjects based on Criteria

DFExplore supports retrieval of subject records based on cross plate criteria. When you click next to the subject ID in a record selection dialog, the subject selection dialog is displayed containing the first subject selection criterion.

DFExplore - Subjects

Select subjects that match ANY of these criteria.

Criterion #1

Status ... Level ...

Visit ...

Plate ...

Field ...

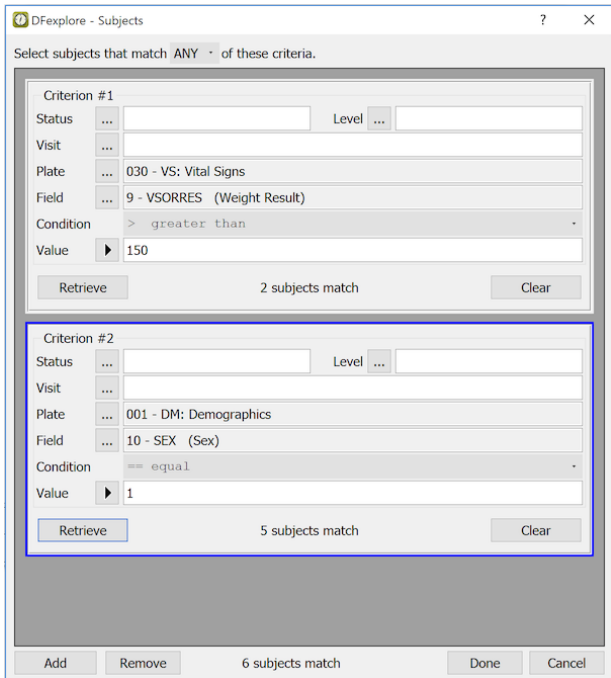
Condition < less than

Value ▶

Retrieve Plate and Field are required Clear

Add Remove 1 incomplete criterion Done Cancel

To add other criterion, click **Add**. To remove a selected criterion, click **Remove**. To see how many subjects match a criterion, click **Retrieve**. To create an intersection of each set of subjects matching a given criterion, set the selection mode to match **ALL** of these criteria. To create a union of each set of subjects matching a given criterion, set the selection mode to match **ANY** of these criteria. In either case, the number of subjects in the set is displayed at the bottom of the subject selection dialog.

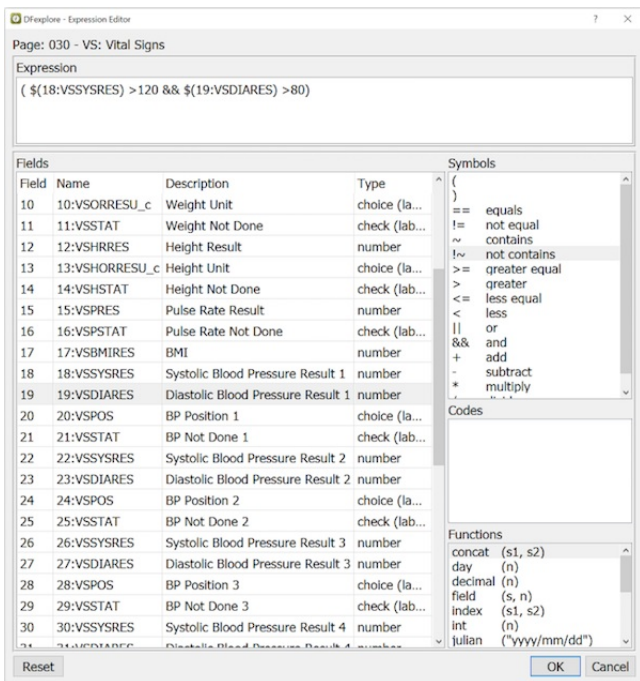


In this example, 2 subjects matched criterion 1, 5 subjects matched criterion 2, and 6 subjects matched either criteria. Click **Done** to return to the record selection dialog.

Expression Editor

DFexplore supports data retrieval from specific plates or modules based on simple algebraic statements describing the desired data records using the Expression Editor.

When a single plate or module has been selected, click **...** next to Expression in the record selection or search dialog to open the Expression Editor dialog, which lists the fields for that plate or module along with the available symbols, codes, and functions. Expressions can be entered directly in the text widget or generated by clicking items in the Fields, Symbols, Codes and Functions panels in the appropriate order.



This example selects subjects with a first systolic blood pressure reading above 120 and a first diastolic blood pressure above 80 on plate 30. Click **OK** to close this dialog and add the expression to your record selection criteria. Click **Reset** to clear the expression.

NOTE: Numeric Codes and Code Labels

Expressions must be created using code labels or sub labels, when labels or sub labels are chosen for display in List View. If numeric codes are being displayed, expressions must test for codes, not labels.

Functions

Several functions are available for use in constructing expressions.

concat(s1,s2)	<p>Test the concatenation of 2 strings. e.g. to find records where the concatenation of 2 fields named 'Mtype' and 'Mnum' combined to give the value 'A1234':</p> <pre>concat(\$(Mtype),\$(Mnum)) == "A1234"</pre>
day(n)	<p>Test for a day of the month in a date, e.g. to find records where 'Screen 1 Date' occurred on or after the 15th of any month:</p> <pre>day(\$(S1DATE)) >= 15</pre>
decimal(n)	<p>Test the decimal component of a number, e.g. to find records where weight is not a whole number:</p> <pre>decimal(\$(WEIGHT)) > 0</pre>
field(s,n)	<p>Test a specified word in a string, e.g. to find records where the 2nd word in a drug name is "ACID":</p> <pre>field(\$(DRUGNAME),2) == "ACID"</pre>
index(s1,s2)	<p>Find the character position in string s1 where string s2 first occurs. e.g. in the following statement local variable 'X' is set to 3:</p> <pre>number X = index("A56GH9","6GH") ;</pre>
int(n)	<p>Test the integer value (truncated) of a field. e.g. to find a subject's current age in years at visit date 'VDATE' using the subject's birth date stored in field 'BDATE':</p> <pre>number age = int((VDATE-BDATE)/365.25) ;</pre>
julian("yyyy/mm/dd")	<p>Determine the julian equivalent to a date, e.g. to find records where 'Screen 1 Date' occurred after Nov.15,2017:</p> <pre>\$(S1DATE) > julian("2017/11/15")</pre>
length(s)	<p>Test field length, e.g. to find initials shorter than 3 characters</p> <pre>length(\$(PINIT)) < 3</pre>
month(n)	<p>Test for a month in a date, e.g. to find records created in June of any year:</p> <pre>month(\$(DFCREATE)) == 6</pre>
substr(s1,n1,n2)	<p>Test a sub-string of a specified field, e.g. to find records where the middle subject initial is "X":</p> <pre>substr(\$(PINIT),2,1) == "X"</pre>
time("hh:mm:ss")	<p>Convert string representation of a time to a time value, e.g. to find records created after 6pm:</p> <pre>time(\$(DFCREATE)) > time("18:00:00")</pre>
today()	<p>Test against today's date, e.g. to find records created today:</p> <pre>julian(\$(DFCREATE)) == today()</pre>

tolower(s)	Convert a string to lowercase, e.g. to find records containing "inuit" in the Race Other field, ignoring case: tolower(\$(RACEOTH)) == "inuit"
toupper(s)	Convert a string to uppercase, e.g. to find records containing "INUIT" in the Race Other field, ignoring case: toupper(\$(RACEOTH)) == "INUIT"
year(n)	Test for a year in a date, e.g. to find records modified in 2017: year(\$(DFMODIFY)) == 2017

CDISC ODM Export

Data can be exported in CDISC ODM format. Select **File** > **CDISC ODM Export...** to display the specification dialog.

DFExplore - CDISC ODM Export

Study: 252 - Demo A Development
 Protocol Name: ABC-252
 Study Description: Demo A Study
 ODM Description: Demo A Study ODM
 Output File: C:/Users/demo_user1/Desktop/ODM_AE_test.xml

Include DFdiscover system fields (1~7,NF-1,NF)
 Use field alias

Meta Data: To modify Study Events, edit numbers or right-click to select from pop-up list

Form#	Form Description	Study Events
<input type="checkbox"/> 101	SE: Subject Encounter	10,20,30,40,50,60,70,80,90,100...
<input type="checkbox"/> 102	SC: Subject Characteristics	0
<input type="checkbox"/> 110	SADH: Study Drug Adherence	10,20,30,40,50,60,70,80,90,100...
<input type="checkbox"/> 120	AA: Acceptability Assessment	10,20,30,40,50,60,70,80,90,100...
<input type="checkbox"/> 130	RCX: Reactogenicity	10,30,50,70
<input type="checkbox"/> 200	MH: Medical History	201,202~209
<input type="checkbox"/> 210	Pain Tolerance	0,1,10
<input type="checkbox"/> 300	CM: Concomitant Medications Log	301-350
<input checked="" type="checkbox"/> 400	AE: Adverse Event	401-450

Select All | Select None | 1 selected | Reset

Clinical Data: select subjects or sites
 Subjects: all

Close this window when export has completed

Clear | Export | Cancel

In the dialog, an **Output File** and at least one visit and plate are required. All plates for which you have permission are listed in the spreadsheet table. If a visit record defined in DFvisit_map is a single visit, the visit number in the **Study Events** column will be green. This green visit number cell is not selectable nor editable. A tool tip will show the visit description. For a range of visits, the visit cells are black and can be modified by typing visit numbers or selecting from the popup list by right-clicking it. If the visit list range is invalid the value becomes red.

Check **Include DFdiscover system fields** to include a module named DFSYSTEM as the first module in each plate. Check **Use field alias** to use the field alias in place of the field name, as defined in **DFsetup**. Metadata can be exported alone (do not check **Clinical Data**) or with plate data (check **Clinical Data**). The output of Metadata will be in the order defined in DFvisit_map.

The plate data will contain completed data only. Fields that are blank, or contain missing value codes, or check/choice fields with the Not Checked code will not be written to the output.

DFdiscover field types will map to ODM types as follows: Number to integer/float, VAS to integer/float, Check/Choice to integer, Date/Time to text, String to text.

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Mimencode

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RSA Data Security, Inc., MD5 message-digest algorithm

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mpack/munpack

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c3.js

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d3.js

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jwt-cpp

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QXlsx

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