



IBCSG

International Breast Cancer Study Group

# DFExplore User Manual Procedures for Participating Centers

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IBCSG Data Management Center

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## Definitions/Acronyms/Abbreviations

Term/Acronym	Definition
Center	Participating Center
CRF	Case Report Form
DMC	Data Management Center (Amherst, USA)
Patient Binder	Compilation of all available CRFs for a patient

## Overview

DFExplore is a remote data entry tool that allows Centers to enter their patient trial data electronically. Remote data entry eliminates the need for faxing most CRFs to the IBCSG. This manual explains the procedures for using DFExplore and DFsend. Use this document and the trial-specific Data Manager's Manual for instructions on how to complete and submit data.

## Getting Access to DFExplore and DFsend

### Download (recommended)

Instructions for downloading DFExplore and DFsend can be found on the IBCSG DF Resource web page at <https://www.ibcsgdmc.org/ibcsg/df/downloads.view>.

### DFnavigator

If you are unable to download DFExplore, it can also be accessed via the web at <https://dfp.fstrf.org>.

DFsend is not available via the web. If accessing DFExplore via DFnavigator, you must fax any non-CRF data into the system. Please see "DFExplore Fax Numbers", available on the IBCSG DF Resource web page, for available fax numbers. You must also enter the sever name each time you use DFnavigator. The server name is "explore.fstrf.org"

The instructions in this manual apply to both the downloaded application and the web-based access.

## Logging in to DFExplore

The DMC provides you with your initial Login Name and Password. You will be prompted to change your password the first time that you log in.

**Your password should not be shared with anyone and is intended for use by only the individual named on the account.**

If you have lost or forgotten your password, either:

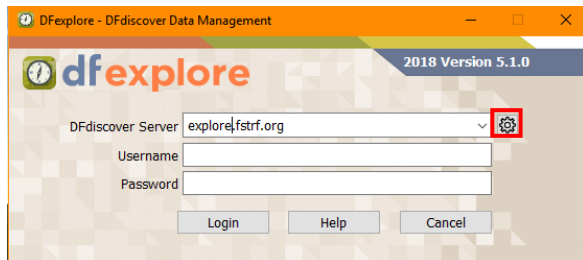
1. Contact [datafax.user.support@fstrf.org](mailto:datafax.user.support@fstrf.org) or
2. Go to: <https://www.ibcsgdmc.org/ibcsg/df/> and click on Support/Reset Password.

A new password will be sent to you within 2-3 business days.

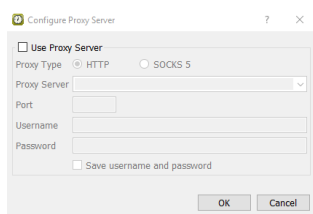
To log in:

1. Double click on the DFExplore icon on the desktop to start DFExplore. The Login box appears. Verify the "DFdiscover Server" field displays "explore.fstrf.org". If not, type it in.
2. Enter your Login Name and Password.

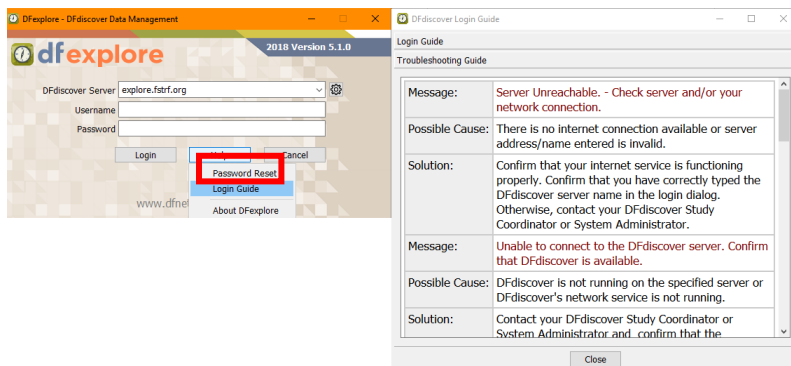
**NOTE regarding Proxy Server:** If your IT department has installed a proxy server (to filter requests sent to other servers on the internet) click the gear button to the right of the ' DFExplore Server' name to register the proxy server. You may need to contact your IT department for the necessary information as your firewall must allow connections to [explore.fstrf.org](http://explore.fstrf.org). The port number used for DFExplore's secure communication is port 443.



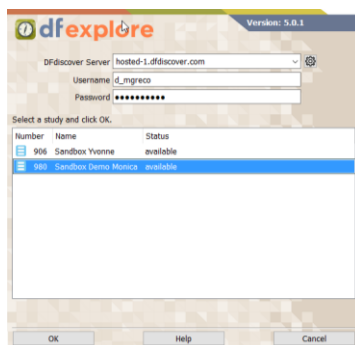
However, if you do not use a proxy server, you should connect directly to our DF server at [explore.fstrf.org](http://explore.fstrf.org) and leave the “Use Proxy Server” box unchecked.



3. The Login box contains a Help button for troubleshooting:



4. Click “Login.” You have officially logged in to DFExplore and a list of trials that you can access is displayed.



5. Double click the appropriate trial or select a trial and click on “OK” or select the trial and press enter on the keyboard.

## Preferences

Once logged in, DFXML has a number of options to view and navigate through the data. To view the options, select "File" -> "Preferences" from the menu bar or the shortcut list on the left side of the Dashboard.

This opens up a Preferences window. There are many options you can choose to set your screens to your preferences. In order to be consistent with the details in this manual, the following settings are recommended.

The screenshot shows the DFXML Preferences window. At the top, it says "Set Dashboard as the default view". Below this, the "Data Window" section is highlighted with a red box. It contains several checkboxes: "Expand all visits when a subject binder is open", "Display first page when a visit is open", "Advance to next field after current field is filled", "Open first task record when task set is built", "Warn before opening next subject when traversing task records", "Retain scroll position when traversing task records", "Display date picker for current date field" (checked), "Auto text alignment for number, date, and time fields", and "Display metadata editor panel" (checked). Below these is a color palette for "eCRF background color" with "#EAEAE1" selected. The "Image Window" section is also highlighted with a red box. It has a checked checkbox "Auto open/close as image is available/unavailable" and a "Display method" section with radio buttons: "toggle screen between data and image views", "split screen: data left, image right", "split screen: image left, data right", "split screen: data top, image bottom" (selected), "split screen: image top, data bottom", and "sticky toggle: retain data or image view across records". The "Background Options" section is highlighted with a red box and contains "Color" radio buttons (black, white, color selected) and a "CRF Type" dropdown set to "AE Monitor". The "Auto Logout" section is highlighted with a red box and shows "Exit after 30 minutes of inactivity". At the bottom are "OK" and "Cancel" buttons.

**Default View:** Set the Dashboard as your default view, to see a real time overview of your Center's data/query submission and quality.

**Date picker:** This allows you to select date from a calendar next to any date field.

**Display metadata editor:** This allows the Query, Reason, Missing Value, and Help-Study box to appear on the right side of the screen. If not checked, the Help box is not displayed.

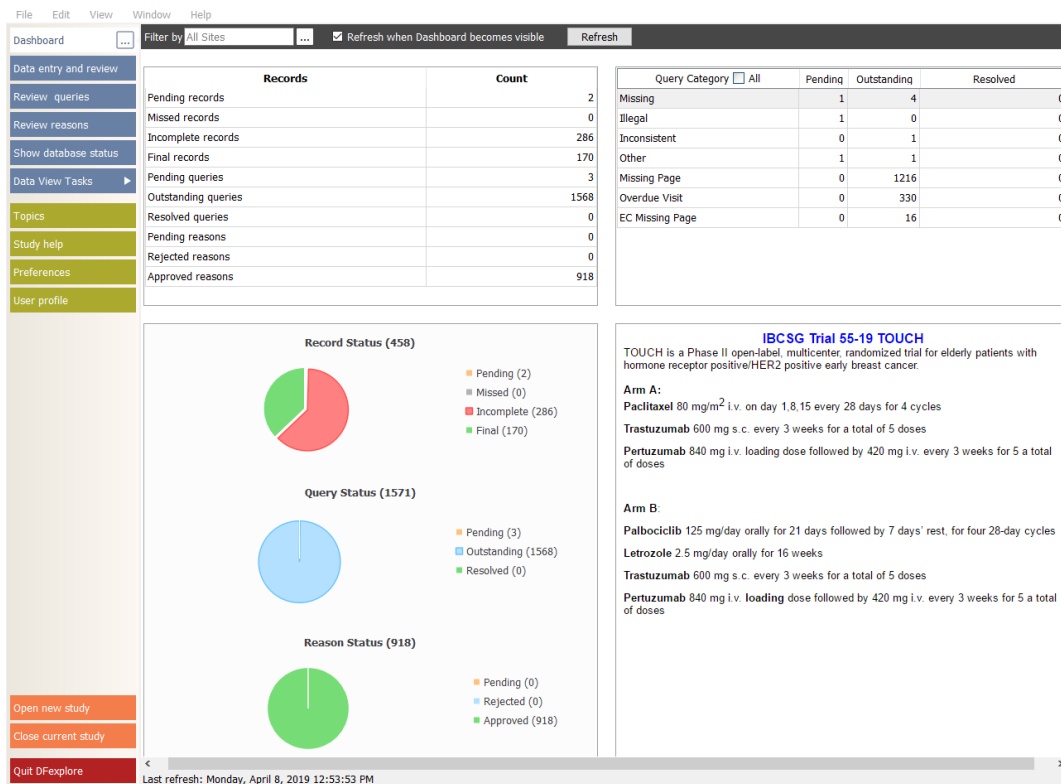
**Auto open/close and split screen: data top, image bottom:** This allows DFXML to display the image of any faxed CRF at the bottom of the screen and the data entered in the database at the top of the screen, so both are visible at the same time. If there is no fax image, you see the database on the full screen.

**Color:** This enables the color features in DFXML. NOTE: For older trials (55 and below), you may want to select white or blank for the background.

**Auto Logout:** This is set, by default, to 5 minutes. You can choose an auto logout time up to 30 minutes.

## Dashboard View

Upon logging in, the Dashboard View is displayed. Dashboard View provides shortcut access to common DFExplore views and a snapshot summary of the current database status. It shows basic study metrics graphically as well as a menu of operations for commonly performed tasks.



**View Shortcuts** - In the left column, shortcuts are provided to commonly accessed functionality and menu items (e.g. data entry, review queries, etc.).

**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. 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.

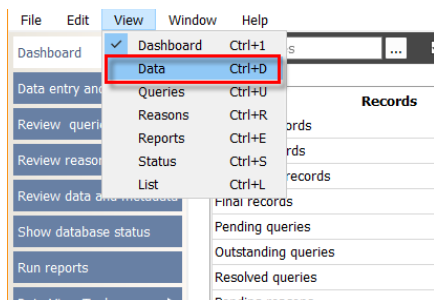
In the table of query categories and statuses, rows are categories (type of query such as missing, incomplete, etc.) and statuses (pending, outstanding, and resolved) are columns. By default, categories (and hence rows) that have counts greater than 0 are displayed. To display all table rows, check "All" 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, you can choose if the task records are displayed in Data View or Queries View.

## Data Entry Details

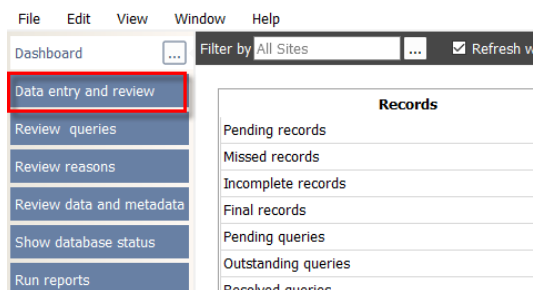
Data entry screens can be accessed two ways:

1. Select "View" from the Toolbar and then "Data".

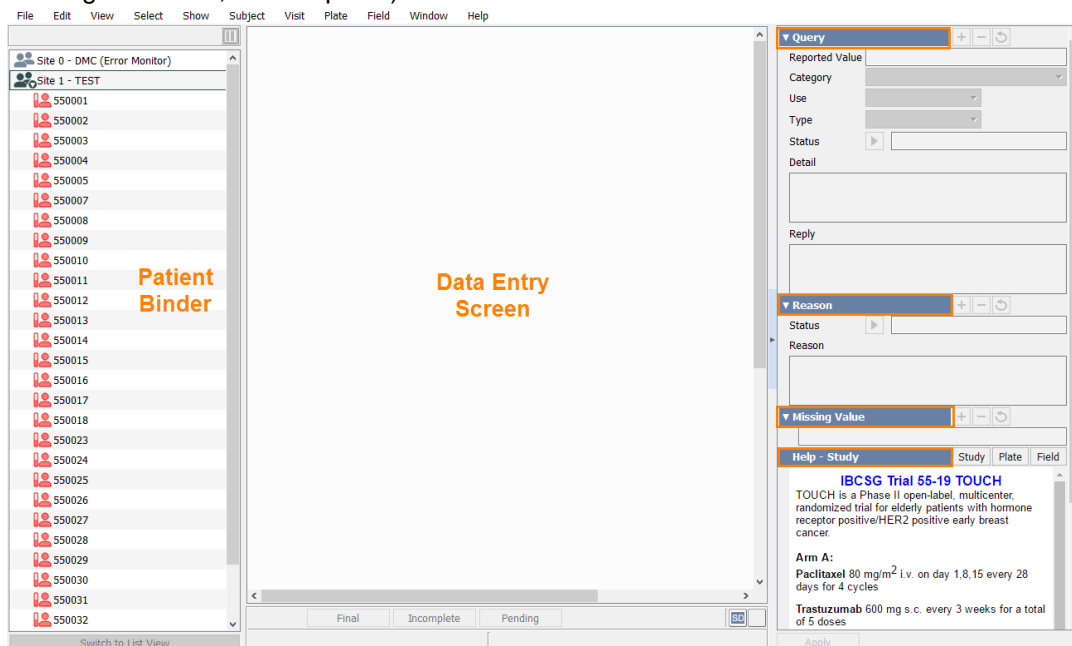


OR

2. From the Dashboard, select "Data entry and review" from the shortcuts on the left:



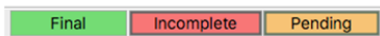
The entry screen consist of six sections (Patient binder, Data entry screen, Query box, Reason box, Missing value box, and Help box):



## Patient Binder

The Patient Binder lists all patients enrolled for that trial, at your Center. Each patient is represented by a Patient ID and, to the left, a head icon.

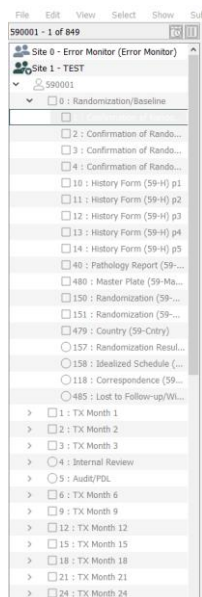
The subject binder colors and icons correspond to the page Save status:



Subject icons:

	Green, filled scale	No problems, all pages with status final
	Red, half-filled scale	At least one page with status incomplete
	Orange, outline scale	At least one page status pending, none incomplete
	Grey, dashed outline scale	All pages marked missed (i.e. unavailable)

Double clicking on the patient icon opens the patient visits and CRFs, ordered by visit (e.g., Baseline, Treatment Cycles, Follow-up, SAEs etc.).



## Data Entry Screen

Data is entered on these screens. Each screen is a page of a CRF. Trials that were set up in iDataFax and migrated to DFExplore (IBCSG 55 and lower) retain the old backgrounds:

**CONFIRMATION OF RANDOMIZATION FORM (Form 55-A)**  
**Instructions:** Complete this form to determine if the patient is eligible for this trial. If the patient is eligible, randomize directly by accessing the IBCSG Registration/Randomization System via the internet. After the patient is randomized, you will be provided with a Patient ID number and randomization date. Record the Patient ID at the top of each page, the randomization date on page 3 and complete in iDataFax.

**Enrollment Eligibility Checklist** (See section 7 of the protocol for details) - Patient status at time of enrollment. Place an "X" in either the No or Yes box for each question.

NO	YES	Question
<input type="radio"/>	<input type="radio"/>	a. Does the patient have histologically confirmed invasive breast cancer defined as: - Early breast cancer with tumor size $\geq 1$ cm (as measured by at least one of the required examination methods of clinical examination, mammography and ultrasonography) - No clinical evidence of regional lymph node metastasis (N0), or nodal involvement limited to clinically detectable metastasis to movable ipsilateral level I, II axillary lymph node(s) (N1) - No evidence of metastasis (M0)
<input checked="" type="radio"/>	<input type="radio"/>	b. Is the patient female and 65 years or older?
<input type="radio"/>	<input type="radio"/>	c. Does the patient have an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1?
<input type="radio"/>	<input type="radio"/>	d. Does the patient's primary tumor express estrogen receptors (ER) $\geq 10\%$ ?
<input type="radio"/>	<input type="radio"/>	e. Is the patient's primary tumor HER-2 positive (by IHC and/or ISH)?



The background color can be changed from black to white by going to File → Preference → Background Options. The white background may aid in viewing the field colors more easily.

Trials set up in DFExplore have a background where colors and shading are used to aid in navigating the questions.

**HISTORY FORM (59-H)**

**Demographics**

1. Age at randomization

**Vitals**

2. Height (cm)  3. Weight (kg)  4. ECOG Performance Status

Do not report decimal

5. Was a pregnancy test performed at screening?

No, not of child-bearing potential  Yes → Date of test

Result of test

If any data is submitted to DFExplore via DFsend or fax, a split screen is displayed where both the fax and the data entry screen are viewable.

**Study 252 (SE) 101 Subject Encounter**

Missed scheduled visit → End of form.

1. Type of visit:

Scheduled → Go to item 2.

Unscheduled

1a. Besides this form, which CRFs were completed for this unscheduled visit? (Mark all that apply or "None")

None  Lab Results

AE  Reactogenicity

CM  Adherence

Vital Signs  Acceptability Assessment

Physical Exam  Other, specify:

1b. Reason for unscheduled visit. (Mark all that apply.)

Adverse Event  Other, specify:

2. Did the subject return study medication?

Yes  No, explain:  → Go to item 3.

---

**DF/Net Study 252 (SE) 101 Subject Encounter**

Missed scheduled visit → End of form.

1. Type of visit:

Scheduled → Go to item 2.

Unscheduled

1a. Besides this form, which CRFs were completed for this unscheduled visit? (Mark all that apply or "None")

None  Lab Results

AE  Reactogenicity


CM  Adherence

Vital Signs  Acceptability Assessment

Physical Exam  Other, specify:

1b. Reason for unscheduled visit. (Mark all that apply.)

Adverse Event  Other, specify:

If the image cannot be seen, you have to select the toggle display box  at the bottom right of the data entry window.

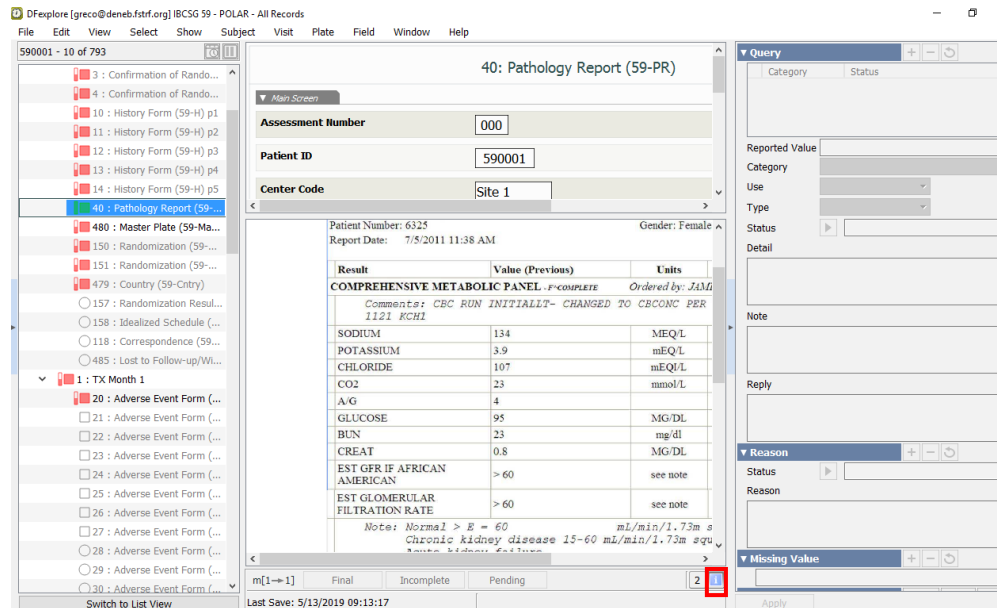
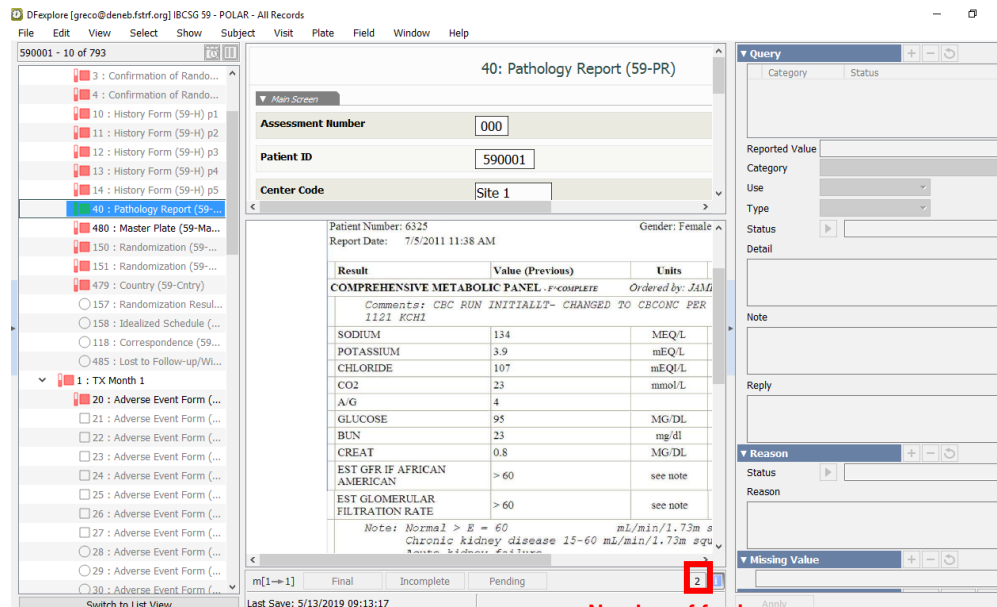


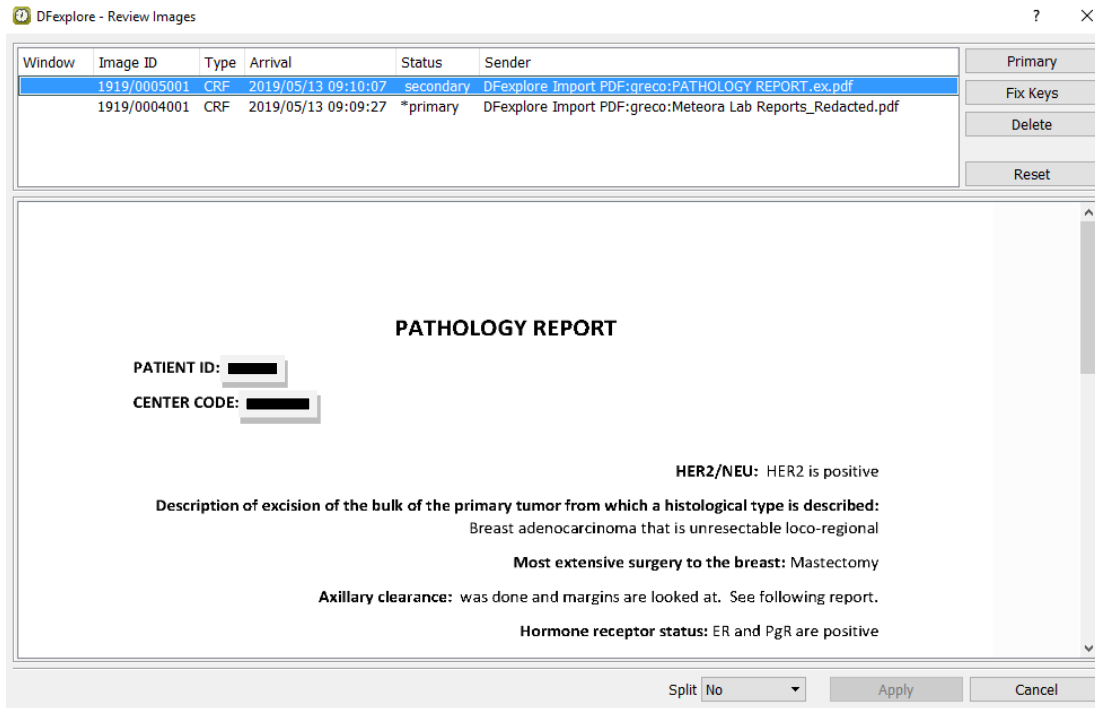
Image display box

If there are multiple pages of an image, these can be pulled up by selecting the numbered box at the bottom right side of the data entry screen.



Number of fax images

The image box expands showing a list of images saved in the database. Click on each one to view each page.



### Query Window

This window is for query management (creation, replying and resolving)

### Reason Window

This window is used to provide a reason when a change is made to saved data. This can also be used to provide additional information or clarification to a data field.

### Missing Value Window

This window is for reporting a value that is unknown, unattainable, etc.

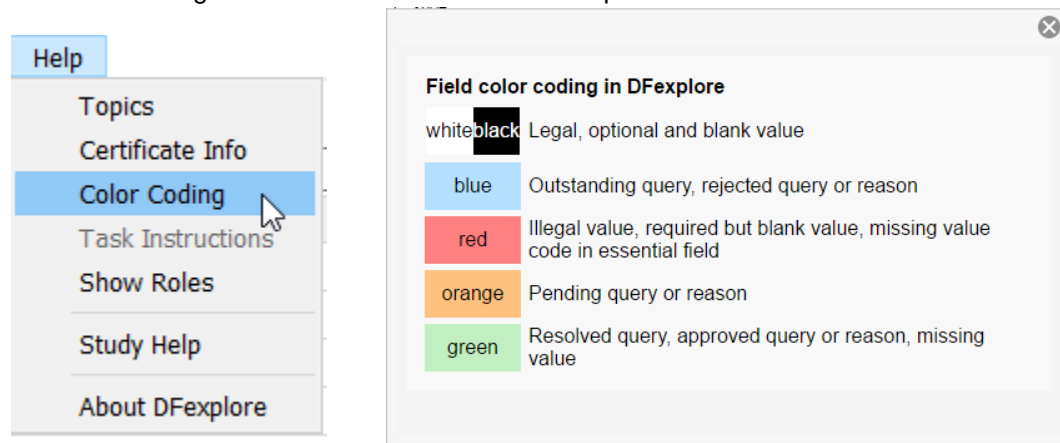
### Help-Study Window

This window provides help at the study, page (plate) and field level.

## Color Coding

DExplore uses different colors to provide information about each field. The chart below explains each color that is used in DExplore.

The color coding chart can be found under the Help tab in the toolbar.



## Entering Data

### Randomization

Within 24 hours of patient randomization via the IBCSG Registration/Randomization system, the patient's binder appears in DExplore.

### Forms Order

All forms for the life of the trial are available in the patient binder. Some forms may not pertain to a specific patient's treatment and therefore, do not need to be completed (for example an SAE form). Do not enter or save changes on CRFs that are in visit periods that have not yet occurred. If this happens, data is requested for the future visits.

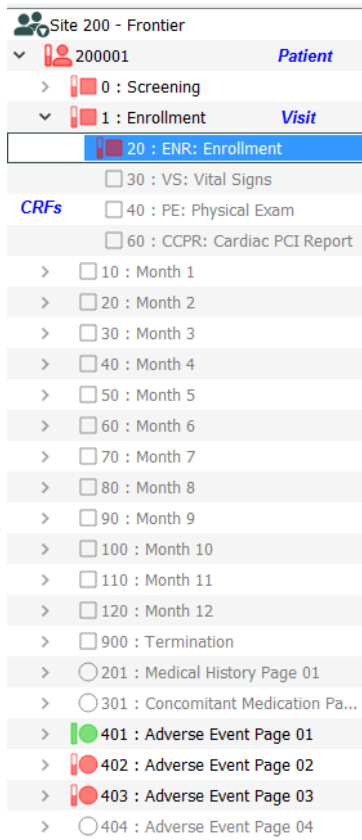
**Example:** A patient is scheduled to come in for the six (6) Month Follow-up visit. If data is submitted for the 18-Month Follow-up instead, the QC report requests all of the data from the time between the 6-Month and 18-Month Follow-up visits.

### Data Entry

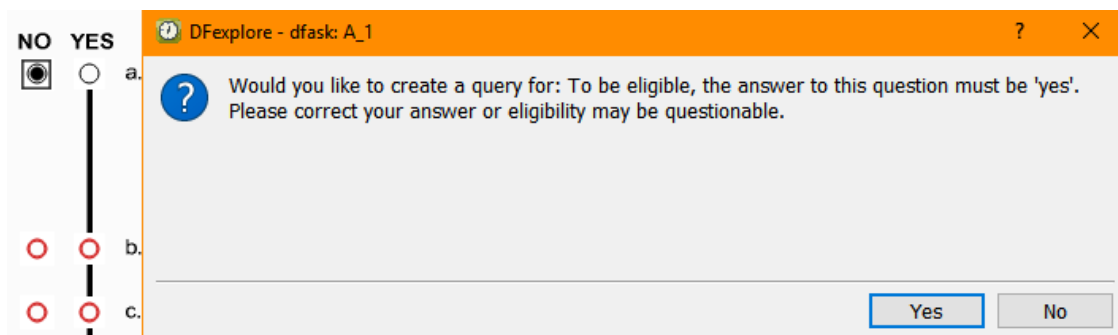
1. Double click the appropriate patient icon to open the binder.

NOTE: If someone already has this patient binder open (e.g., DMC managing data) you will not be able to enter data. A dialogue box pops up stating the patient is locked by another user and asks if you want to review the data in View Only Mode.

2. Double click on the appropriate visit. The visit expands and all forms available for that visit are displayed.

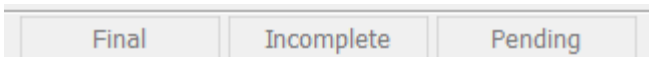


3. Click on the appropriate form. The form opens in the data window.
4. Each field should be navigated by using the Tab key so auto-populations and warnings, if applicable, can pop up and prompt you to either enter or correct data. This dialog box explains the inconsistency and prompts you to correct the problem.



5. You can decrease the number of queries from the Data Management Center if you correct the data before it is saved.
6. If you do not correct the inconsistency, the page can still be saved. The inconsistency is brought to the Center's attention again once the DMC has reviewed the page and added a query.
7. Save the page when all necessary questions are answered. You must save each page after data entry is complete. When the record is saved it is automatically sent to the DMC for review. There are two (2) different save modes:

- **Final:** The record can be saved as Final when there are no outstanding fields, queries, or inconsistencies on the page. If there are outstanding problems on the record (any red or blue fields), the “Final” box is gray and you can’t click it. Records saved as Final appear in the patient binder with a head icon colored green.
- **Incomplete:** Save the record as Incomplete when there are outstanding data, queries, or inconsistencies that still must be resolved. Records saved as Incomplete appear in the patient binder with a head icon colored red.



**NOTE:** Records saved as Incomplete are submitted to the DMC with the inconsistencies. The Center may return to the record and add additional information at any time. If changes are saved, the amended form is re-reviewed at the DMC. See the **Correcting Data** section for more information.

**NOTE:** Illegal values on the record can only be saved as Incomplete. For example a value outside the normal range or a partial date.

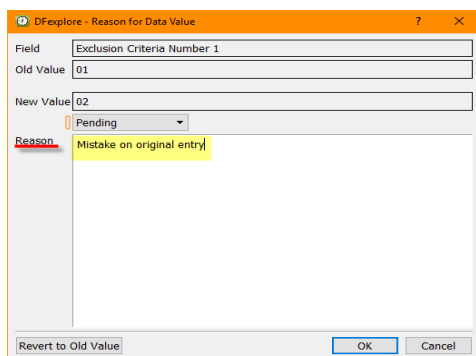
**NOTE:** The Pending option appears on the Save Bar, but cannot be used.

### View Only Pages

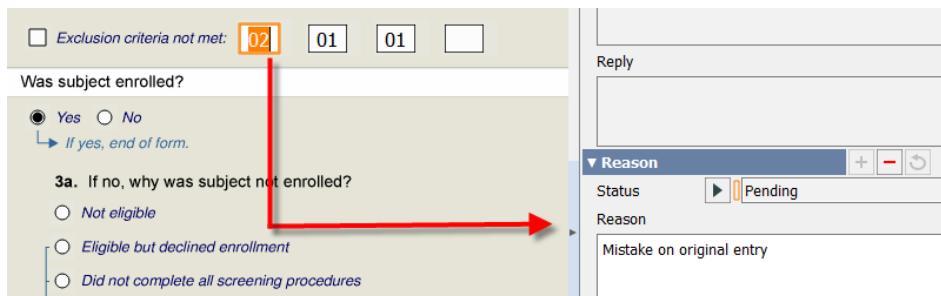
Pages marked “**view mode**” at the bottom of the data screen are pages you cannot make changes to. The page may be for internal use at the DMC or it may be that all pages are locked because another user has this patient’s binder open already.

### Entering a Reason for Changing Data

Once data has been saved, it cannot be changed without entering a reason for that change. If you change data in a previously saved field, a dialogue box appears prompting you to enter a reason:



Enter the reason for change and click OK. If you did not mean to make the change, click Revert to Old Value. If you click OK, the field turns orange (pending DMC review) and the reason is viewable to the right of the screen:

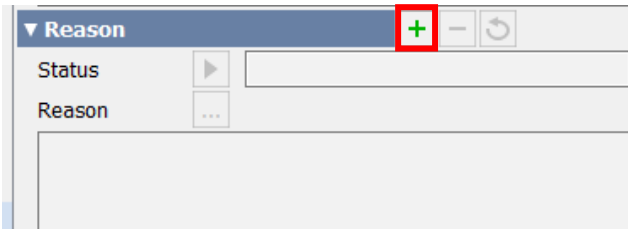


Once the reason is reviewed by the DMC, it is approved and the field turns green, or it is rejected and a query is added, turning the field blue.

### Clarifying an Answer

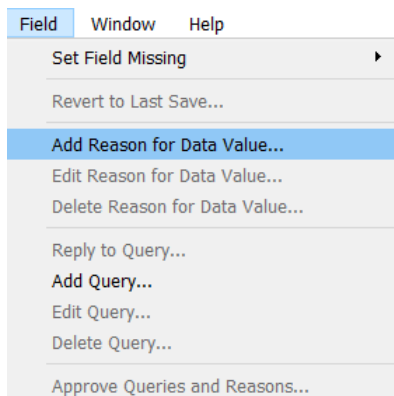
When completing a CRF, you may provide an explanation for unusual or missing data (e.g., question was not asked, procedure done at another institution, lab values abnormal due to chemotherapy, etc.) by using the Reason for Data Value Box. This additional information may eliminate the need for a query. To enter a reason:

1. Click on the field for which a reason is being provided.
2. Click the green + button in the Reason box title bar. This launches a text box.



OR

1. Click on the Field option in the top toolbar and select "Add Reason for Data Value". This also launches a dialogue box.



2. Type the reason in the text box.
3. Click OK to save the reason. The field turns orange, indicating that a reason has been entered and must be reviewed by the DMC (pending reason). If the DMC approves the information in the Reason box, the field turns green. If the DMC has additional questions, a query is issued or the reason is rejected, and the field turns blue.
4. Save the record before navigating off the current plate. A warning message will pop up if you try to move to a new record without saving the changes.

### Additional Options

After a reason has been saved onto a field, it can be either changed or deleted.

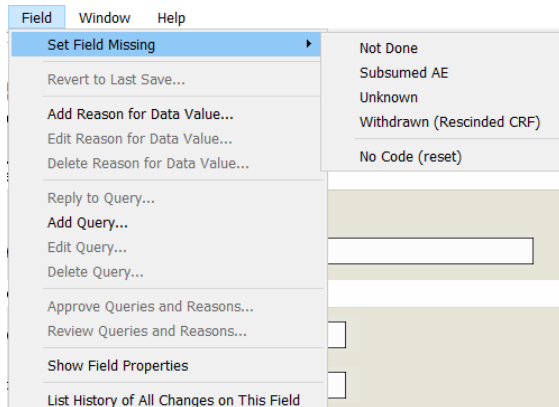
1. Click on the field in where the reason was entered.
2. In the toolbar at the top of the screen, click on "Field" tab.
3. Select "Edit Reason for Data Value" to change the reason (in the dialogue box that pops up) or select "Delete Reason for Data Value" to **remove the reason from the field**.

## Missing Values

If an answer to a question is unknown, not done or unattainable, this can be noted using the Missing Value function. Fields can be marked as missing one of two ways:

### Option 1

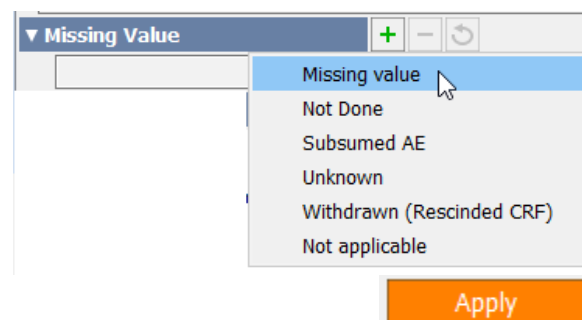
1. Click on the field in question.
2. In the toolbar at the top of the screen, click on “Field” tab.
3. In the drop down menu, Click “Set Field Missing’ and choose the appropriate reason the field is not answered. This changes the field to green.



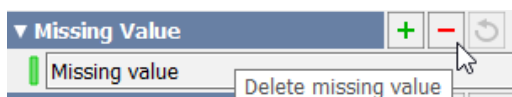
If at any time you wish to enter data in these fields, follow the steps above and then select “No Code (reset)” to change the field back to its original color and enter data. Data cannot be entered if the field has been marked as a missing value.

### Option 2

1. Click on the field in question.
2. Click on the green + sign in the Missing Value box.
3. Select the reason the question cannot be answered. This changes the field in question to green.
4. Click apply at the bottom right of the screen.



If at any time you wish to enter data in this field, you need to remove the missing value coding. To change the field back to its original color and enter data, click on the red minus sign then click on the Apply button.



**NOTE:** Fields that have been marked with the missing value do not allow data to be entered. The code must be deleted/reset in order to enter any data.



## Partial Dates

Partial dates are considered illegal (red field) by DFExplore. However, if the date is viewed as valid (not required for eligibility, progression, or serious adverse event reporting) by the DMC, it is accepted and the field changes to green.

If the month and year are known but the day is unknown, 00 can be entered for the day. For example, if the date is May 2011, 00/05/2011 should be entered in DFExplore.

If only the year is known and the day and month are unknown, 00 should be entered for both the day and month. For example, if the date is 2011, 00/00/2011 should be entered in DFExplore.

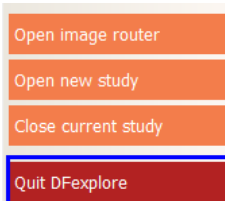
If the entire date is unknown, the field should be marked as a Missing Value. **Do not enter an unknown date as 00/00/0000.**

Dates are reported in dd/mm/yyyy format in DFExplore and on the CRFs.

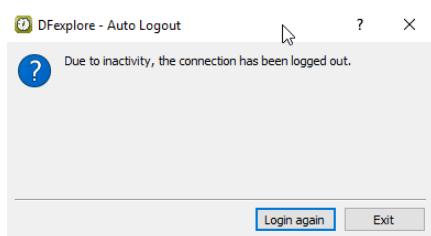
## Logging Out of DFExplore

1. Save any changes to the current page as final or incomplete.
2. If changes are not saved, DFExplore displays a dialog box prompting you to save any changes.
3. Select "File".
4. Select "Exit".

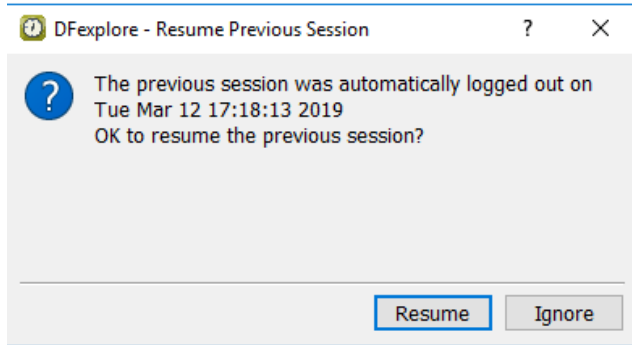
You can also log out from the Dashboard View by clicking the "Quit DFExplore" tab on the bottom left.



1. If after a period of inactivity you are automatically logged out, and the Auto Logout box appears. To return to DFExplore, click "Login again." To exit DFExplore, click "Exit."



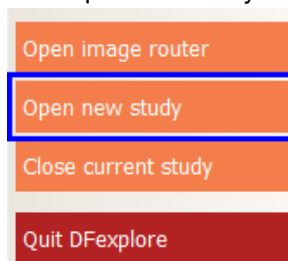
2. If you were automatically logged out, a dialog box appears the next time you log in to the same trial. You may return to the same page you were on before you were logged out. Click "Resume" in the dialog box to return to the last page. If there were unsaved changes on this page, the dialog box identifies the appropriate Patient ID, assessment number, and page number. If you do not want to return to the last page click "Ignore".



## Switching Between Trials

If your Center participates in more than one trial in DFExplore, you may close out of one trial and open another by doing the following:

1. Save any changes to the current page as final or incomplete.
2. If changes are not saved, DFExplore displays a dialog box prompting you to save any changes.
3. Select "File".
4. Select "Close Study" or "New Study". If in Dashboard view, you can also do this by clicking on the "Open new study" tab on the bottom left".



5. This displays the initial Lists of Trials. You can now open another DFExplore trial by double clicking on that trial.

You can have more than one trial or multiple instances of the same trial open at the same time in DFExplore. Multiple sessions of DFExplore can be opened to look at different patients.

## DFsend

Some information cannot be entered electronically in DFExplore. Some examples are:

- Quality of Life/Patient-completed questionnaires
- Reports: Pathology, Laboratory, Autopsy, etc.
- Medical Review query replies: These are queries generated by the IBCSG Medical Reviewers and sent via email. They must be completed by hand.

This information must be submitted by DFsend (preferred) or fax. Once received and entered by the DMC, these forms/reports are viewable, but not editable, in DFExplore.

### Using DFsend

Be sure you have downloaded DFsend from <https://www.ibcsghdmc.org/ibcsgh/df/downloads.view> .

If you are using DFnavigator instead of DFExplore, you cannot use DFsend. You must send this type of information via fax. The fax numbers are available on the DF Support page at <https://www.ibcsghdmc.org/ibcsgh/df/documentation.view> .

1. Login with the same server (explore.fstrf.org), username and password you use for DFExplore.

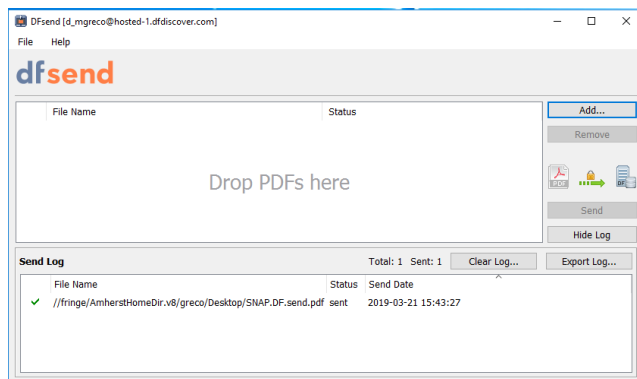
2. Document selection – **The files must be saved in PDF format.** Drag and drop one or more PDFs onto the DFsend application box or click the Add button to use the standard file selection dialog.

**NOTE:** All pages must have the patient's Randomization ID Number and Center Code written clearly on them or we are unable to identify the pages and they cannot be routed to the patient's file.

For Pathology and other reports, all other patient identifiers must be crossed out. Each trial has label templates that can be printed and affixed to these types of reports, which can help the DMC identify them. These label templates are available on the IBCSG web site or the CTSU/Alliance website.

3. Transmit - Click the Send button to send the selected PDFs to the study server. Enter your username and password again for verification.
4. Confirmation - On completion, DFsend displays the transmission status of each PDF file. A green checkmark indicates a successful transmission where as a red X indicates a failed transmission.
5. Tracking - Each PDF transmission is logged by: username, date, time and transmission status. This information is readily available when viewing pages in the DFExplore electronic patient binders. Past transmissions can be reviewed in the DFsend application by selecting the option "Show log".

## Quality Control (QC) Reports



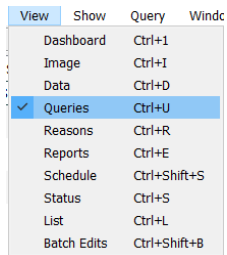
Quality Control Reports are distributed on a regular basis via e-mail to the individual Center or Coordinating Group who, in turns forwards them to the Centers. The Report contains a list of overdue forms and, for some trials, a patient summary status. With DFExplore you can view overdue queries and CRFs in real time and have a chance to answer them before the next QC Report is generated.

For older trials Centers' outstanding queries may also be sent. You can either answer the queries on paper and send the response back via DFsend or fax, or answer the queries directly in DFExplore. **You do not need to do both.**

We recommend you check for and answer outstanding queries regularly, so data can be clean. See **Answering Queries** below for more information.

## Checking for Queries

1. Click the “View” drop down menu on the tool bar.
2. Select Queries.



3. Alternatively, queries may be selected from the Dashboard View in one of two ways. Clicking on the Outstanding queries column takes you to the individual queries on the data field.

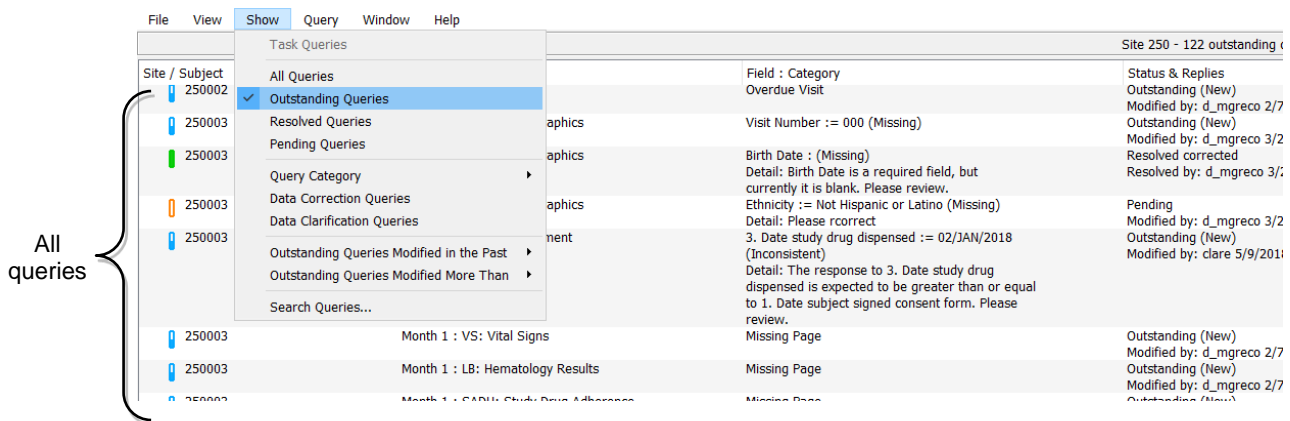
The screenshot shows the 'Data entry and review' dashboard. On the left, there is a sidebar with buttons: 'Review queries' (highlighted with a red box), 'Review reasons', 'Review data and metadata', 'Show database status', and 'Run reports'. The main area contains a table with columns 'Records' and 'Count'. Below it is a summary table for 'Query Category' with columns 'All', 'Pending', and 'Outstanding' (highlighted with a red box).

Records	Count
Pending records	2
Missed records	0
Incomplete records	286
Final records	170
Pending queries	3
Outstanding queries	1568
Resolved queries	0

Query Category	All	Pending	Outstanding
Missing		1	4
Illegal		1	0
Inconsistent		0	1
Other		1	1
Missing Page		0	1216
Overdue Visit		0	330
EC Missing Page		0	16

4. Using View→ Queries or clicking on “Review Queries” on the left, shows queries as follows:
  - 4.1. A list of all queries for all your patients on the trial are displayed. Queries with a green icon have been resolved and require no further action. Queries with a blue icon require a reply from you. Pending queries are indicated with an orange icon. These are awaiting DMC approval.
  - 4.2. You can narrow the list of queries are displayed (e.g., all queries, only outstanding ones, etc.).
    - Select the “Show” drop down menu on the tool bar.
    - Select the desired option.



Site / Subject	Visit : Page	Field : Category	Status & Replies
Site 200 - Frontier			
200001	Screening : DM: Demographics	Birth Date := 02/JAN/1985 (Illegal)	Outstanding (New) Modified by: kitty 1/23/2019 18:27:40
200001	Enrollment : ENR: Enrollment	Visit Date : (Missing) Detail: TEST Query	Outstanding (New) Modified by: KScott 2/8/2019 11:58:15
200001	Adverse Event Page 02 : AE: ???	SDV Check := Unchecked (SDV Query) Detail: SDC Review Required	Outstanding (New) Modified by: KScott 12/3/2018 11:45:36
200001	Adverse Event Page 03 : AE: ???	SDV Check := Unchecked (SDV Query) Detail: SDC Review Required	Outstanding (New) Modified by: KScott 1/17/2019 08:20:59

Outstanding queries only

4.3. Double clicking on an individual query line opens the patient binder to the CRF page that has the query and the field where the query is placed. The query can then be answered.

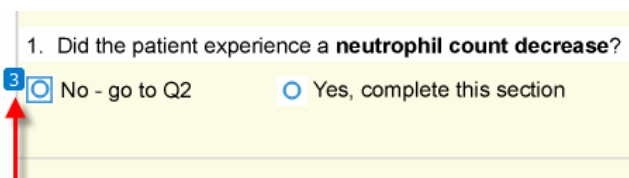
4.4. To return back to Query View, click on the “Return to Query View” bar located below the patient binder.



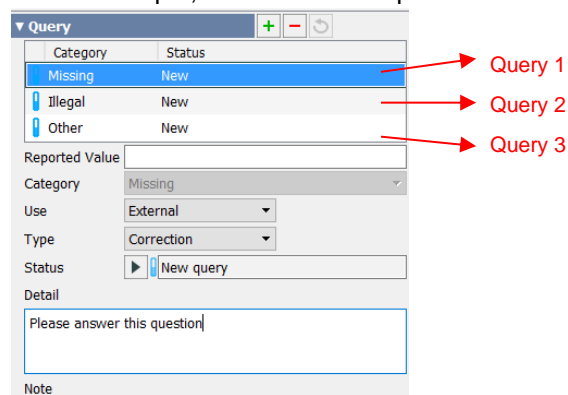
5. When you are done with Query View, you can return to the patient binder by selecting “View” from the tool bar and then click on “Data”.

### Answering Queries

Fields that have queries associated with them are highlighted blue. If there is more than one query on a field, it is noted as follows:



In this example, there are three queries that need to be answered. The Query box lists all 3 queries:



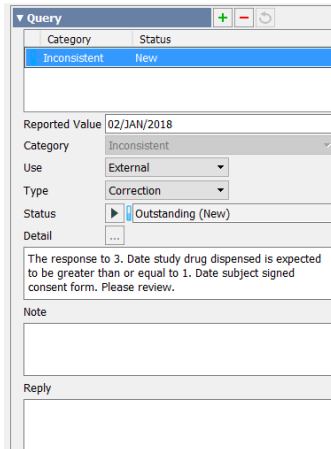
All three queries need to be answered. There are three ways to reply to queries.

1. Correct the data.

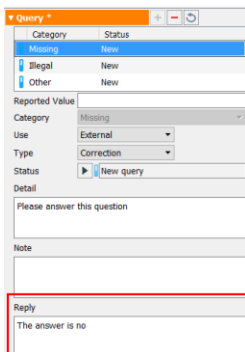
If the query is asking for missing data, or a data correction, you can correct the data in the field and save the page. If you do this, you do not need to answer the query. The DMC reviews the data change and resolves the query if answered adequately by this change or addition.

2. Use the Query dialogue box

- Click on the field being queried. The query is displayed in the Query box on the right side of the window.



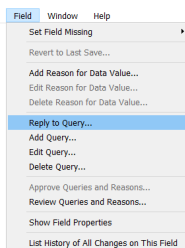
- Type your answer in the Reply box.



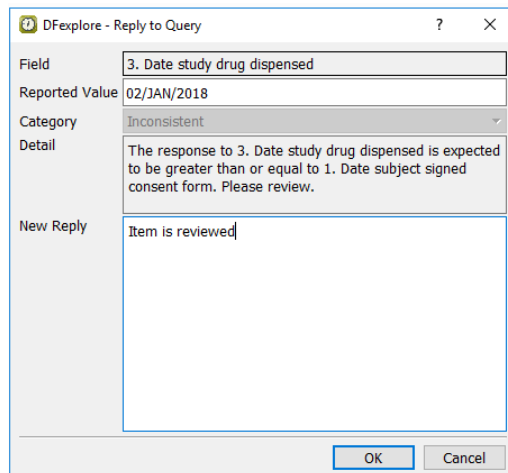
- Click "Apply" at the bottom of the screen. The field turns orange. When the DMC reviews and resolves the query, the field turns green. If further clarification is needed, the DMC writes a new query which changes the field back to blue and requires another response from the Center.

3. Reply to Queries from the toolbar:

- Click on the field being queried.
- Select "Reply to query" from the Field tab.



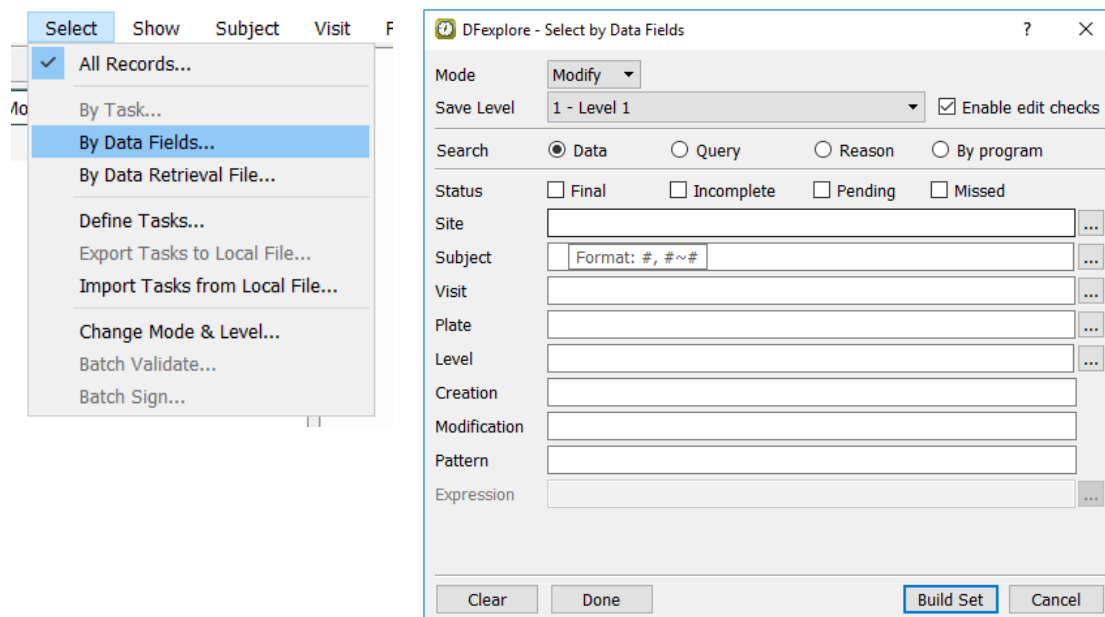
- A dialogue box is displayed:



- Enter a reply.
- Click “OK”. After resolving the query, the field turns orange. When the DMC reviews and resolves the query, the field turns green. If further clarification is needed, the DMC writes a new query which changes the field back to blue and requires another response from the Center.

## Data Field Section

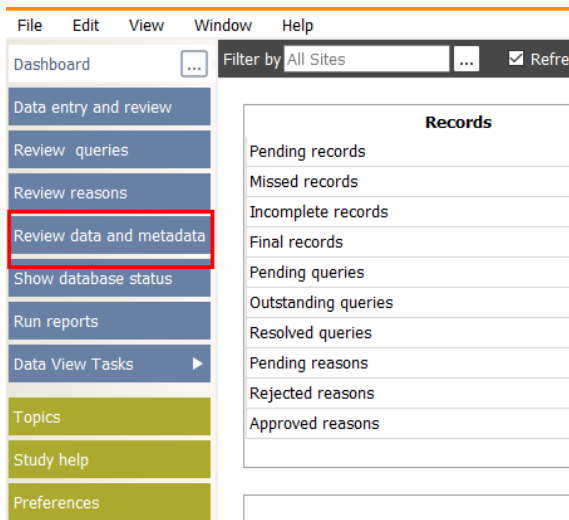
To select specific data fields go to the “select” tab on the menu bar. Choose the option “by data fields”. This brings up a tool box for field selection options. This is how you pull up a single patient binder or an entire Center.



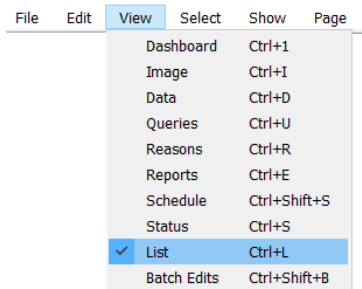
## List View

List View allows you to view data records for a selected CRF page in spreadsheet form for all your patients. Each row in the spreadsheet is a data record and each column is a data field. This data can be searched and sorted. In list view, the data can be exported (Click File → Export Data) to various Excel formats.

You can access list view from Dashboard View by clicking on the Review Data and Metadata tab.



List View can also be accessed from the toolbar at the top; Select “View” and then “List”. This opens up a window showing all CRF pages available for that trial.



When one page is selected, a table replaces the data window. The table lists each field on the page and the data entered in DfExplore for each patient.

The screenshot shows the DfExplore List View interface. The top menu includes File, Edit, View, Select, Show, Page, Field, Window, and Help. The left-hand navigation menu shows 'Plates & Metadata' and 'Modules'. The main content area displays a table of patient data for a specific CRF page. The table has 14 columns: DFSTATUS, DFVALID, DFRASTER, DFSTUDY, DFPLATE, VISITNUM, SUBJID, VISDAT, MHSPID, MHTERM, MHSTDAT, and MHENDAT. The first row is highlighted in red.

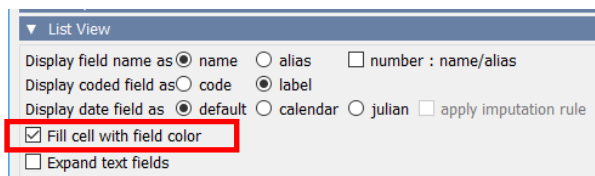
	DFSTATUS	DFVALID	DFRASTER	DFSTUDY	DFPLATE	VISITNUM	SUBJID	VISDAT	MHSPID	MHTERM	MHSTDAT	MHENDAT
1	final	1st Pass Entry	1737R001G001	252	200	201	250001		20101	SEPSIS	12/MAR/2000	12/MAY/2000
2	final	1st Pass Entry	1819R002P014	30	200	201	250005	04/MAY/2017	20101	left knee sprain	03/APR/2017	
3	final	1st Pass Entry	1819R002P034	30	200	201	250007	01/MAY/2018	20101	right arm fracture	23/JUN/2002	15/NOV/2002
4	final	1st Pass Entry	1738R0006029	252	200	201	350001		20101	Obstructive sleep apnea	02/MAY/2009	
5	final	1st Pass Entry	1738R000M007	252	200	201	350003		20101	Tubal ligation	00/000/1997	00/000/1997
6	final	1st Pass Entry	1738R000N001	252	200	202	350003		20201	Pancreatitis	00/000/2001	00/000/2001
7	final	1st Pass Entry	1819R003G008	30	200	201	350004	01/MAY/2018	20101	asthma	06/JUN/1990	
8	final	1st Pass Entry	1819R003H032	30	200	201	350005	01/JUN/2017	20101	flu	04/FEB/2017	15/FEB/2017
9	final	1st Pass Entry	1819R003J018	30	200	201	350008	01/FEB/2016	20101	pneumonia	23/JAN/1991	12/FEB/1991
10	final	1st Pass Entry	1819R003H076	30	200	201	450007	01/MAY/2018	20101	arthritis	08/SEP/2013	

No data can be changed or entered in List View. “View Mode” appears at the bottom of the screen to remind the DM of this.

Any column can be reordered in ascending or descending order by clicking on the field in the top row. Double clicking on any field in the table takes you back to Data View where the page/data can be seen and amended.

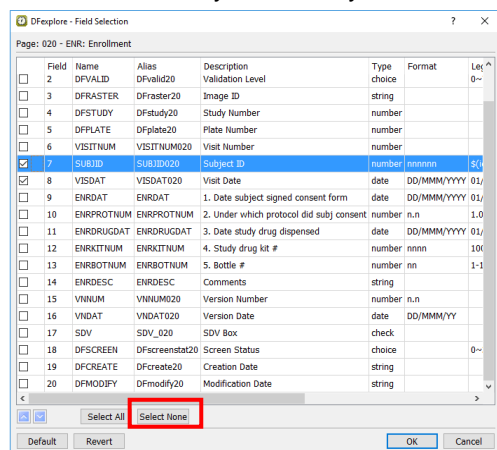


The fields can also be color coded to match the data (blue for fields with queries, green for resolved field, etc.). To activate this option, choose “File” from the tool bar and “Preferences” from the drop-down menu. Under “List View” click on “Fill cell with field color” and then click “OK”.



All fields on that page are displayed in a line; one line per patient. To reduce the number of fields seen, click “Select” from the toolbar and then “Field Selection”. A pop up box with all the fields is displayed.

Click on “Select None” and then individually select the fields you want to review. Then click “OK”. The screen shows only the fields you selected.

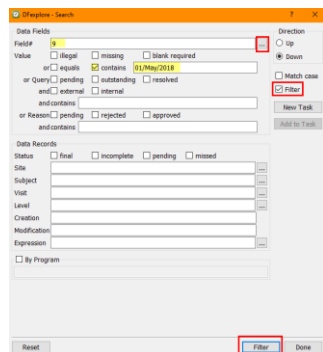


### Searching a Field in List View

The Search function in List View can be used to find records with a specific data value or attribute.

1. While in List View, select the plate you would like to search.
2. Choose “Select” from the toolbar and then “Search”.
3. Click on the “...” button next to the Field # box, and choose the field you would like to search.
4. Specify the data you are searching for, check the “Filter” box and click “Filter”. A dialogue box pops up with the results of the search. To view these filtered records, click “Apply”.

The example below is a search on an Enrollment Form. It is looking for all patients that were randomized on 01/May/2018.



The records you selected appear in the window.

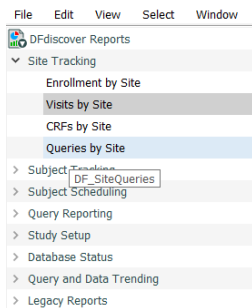
Plates & Metadata	Modules	DFSTATUS	DFVALID	DFRASTER	DFSTUDY	DFPLATE	VISITNUM	SUBJID	VISDAT	ENRDAT	
[250007,1,20] - 1 of 2 filtered records		1	final	1st Pass Entry	1819R002P020	30	20	001	250007	01/MAY/2018	01/MAY/2018
001 - DM: Demographics 010 - IE: Inclusion Exclusion 020 - ENR: Enrollment		2	final	1st Pass Entry	1819R003H066	30	20	001	450007	01/MAY/2018	01/MAY/2018

## Reports

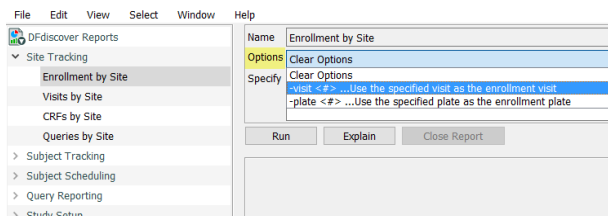
DExplore has many reports that can help present overall pictures of compliance, accrual, etc.

To run a report, select “Reports” from the “View” tab or select “Run Reports” from the Dashboard View. A list of report options appears.

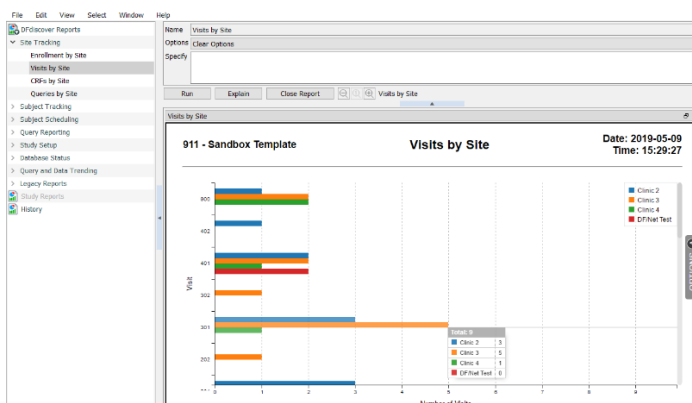
Some reports are accessible based on role permissions. You may not be able to run these reports and they will not be in the list when you open the Reports menu.



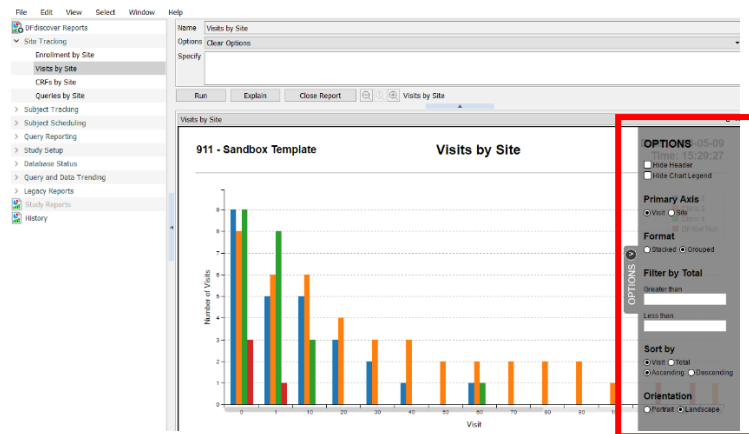
Click on a report option. Select the data options in the drop down to specify the report. Once the options are specified, click “Run”.



The reports are interactive and clickable output can be manipulated and displayed in diverse ways without re-executing the report. They can be pulled off the DExplore screen (click on the report and drag it off DExplore window) and you can continue to work in the database. Reports can be printed and saved in different formats.



If you select Options on the right side of the report, additional features can be viewed.



Reports can be saved in PDF, Excel, and HTML formats.

## Saving Data from DFExplore

You can save blank forms for each patient to use as a worksheet, or copies of completed forms for reference as PDF files. A single page or the entire binder can be saved.

**NOTE:** Files saved as PDFs are not viewable by the DMC. Saved files are to be used for Center reference only.

1. Open the appropriate patient binder.
2. Select "File".
3. Select "Save as PDF".
4. Select the appropriate options (see Printing from DFExplore for descriptions of most of the options)

5. After desired options have been selected, click on the button in the Output File section to choose the location to save the file.
6. Click "Save".

## Printing from DFExplore

While saving data as a PDF is more environmentally friendly and can reduce the risk of HIPPA violations, you also have the option to print blank forms for each patient to use as a worksheet, or copies of completed forms for reference. A single page or the entire binder can be printed.

1. Open the appropriate patient binder.
2. Select "File".
3. Select "Print".
4. Select the appropriate options:
  - 4.1. The Selection Criteria section allows you to determine how much of the patient binder will be printed:

**Blank CRF books:** Allows you to print blank CRFs by patient, visit or page (plate)

### Data and images

- **Current Plate:** Prints only the page that is open in the data window.
- **Current Visit:** Prints all pages in the visit period that is open in the data window.
- **All Open Visits:** Prints all pages in every open visit period (i.e., all CRFs for that assessment can be seen).
- **Current Subject:** Prints all pages in the selected patient binder.

- 4.2. The Print Options section allows you to determine what types of images are printed:

**Blank plates (pages):** Prints a blank copy of the selected pages.

**NOTE:** The Patient ID and Month/Cycle/Visit Number are completed on every printed page, even if "Blank Pages" is selected. Verify that the correct patient binder is selected before printing.

**Data records:** Prints pages with data. The data and primary (data submitted by DFsend or fax) images can be printed side by side.

**Images:** Prints any images submitted by DFsend or Fax. If more than 1 image is held on the same page, one image is assigned as primary and all others are secondary. If you want to print all images for that page, select "all images".

**Color Option:** Clicking this box applies the colors for each field (e.g. blue for outstanding query, red for required/illegal field, etc.)

5. Click "Print".

## User Support and Contact Information

For questions related to trial-specific issues, contact the DMC at the appropriate email address.

DFExplore resources, support, and documentation are available at: <https://www.ibcsgdmc.org/ibcsg/df/>  
For fax confirmation and technical questions about DFExplore or connection issues, contact DMC user support at [datafax.user.support@fstrf.org](mailto:datafax.user.support@fstrf.org) or via phone at +716-834-0900 ext. 7302.