



IBCSG

International Breast Cancer Study Group

DFexplore User Manual
Procedures for Coordinating Groups
View-Only Access

Version 2.0

May 2022

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
Patient Binder	Compilation of all available CRFs for a patient
QC	Quality Control
EDC	Electronic Data Capture

System Overview: DFExplore and DFsend

DFExplore is a remote data entry tool that allows Centers to enter their patient trial data electronically and allows Collaborative Groups to view the data that has been submitted to the IBCSG by their Centers. This manual explains DFExplore View-only access and DFsend. Those that have view-only access will not be able to change data or reply to queries in DFExplore.

A Coordinating Group may be responsible for submitting non-CRF data to DFExplore for their Centers. DFsend is a simple internet app used to send PDFs (containing scanned data forms, reports and other non-CRF documents) to the DMC for review and processing. It includes the authentication, encryption, confirmation and tracking needed to meet today's security and regulatory requirements, and provides a cost-effective alternative to faxing.

System Requirements and Recommendations

Internet Connection Speed: A minimum of a DSL connection is recommended for DFExplore. A slower connection will result in slower response times.

Operating System: DFExplore is available for direct installation on Windows 8 and 10, MacOS 10.12 and newer.

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 be accessed via the web through DFnavigator at <https://dfp.fstrf.org/>

NOTE: 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 server name each time you use DFnavigator. The server name is "explore.fstrf.org".

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

DFExplore resources (including installation files), support and documentation are available at:
<https://www.ibcsqdmc.org/ibcsq/df/>.

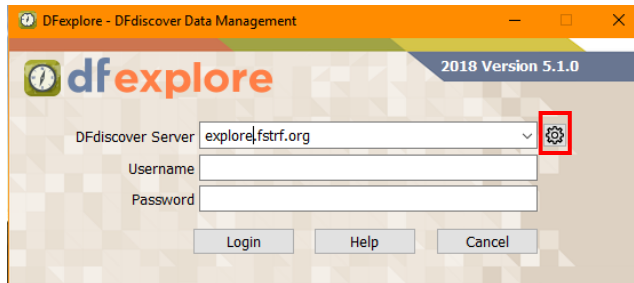
For trials using DFExplore, resources are also available on the IBCSG Member website, on the trial-specific webpage under General Resources.

Logging in to DFExplore

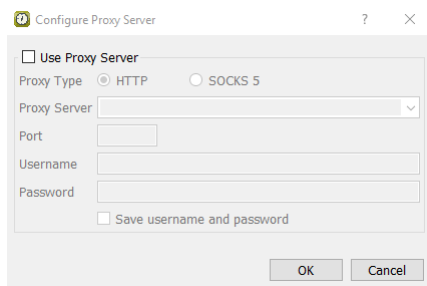
1. The DMC provides you with your initial Login Name and Password. You will be prompted to change your password the first time that you log in. If you have a Login Name and password from iDataFax (iDF) assigned prior to June 2019, your iDF Login Name and password can be used for DFExplore. Every 90 days, DFExplore displays a prompt to change your password.
2. Your password should not be shared with anyone and is intended for use by only the individual named on the account.
3. If you have lost or forgotten your password, either:
 - Contact datafax.user.support@fstrf.org or
 - Go to: <https://www.ibcsqdmc.org/ibcsq/df/> and click on Support/Reset Password
4. 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.

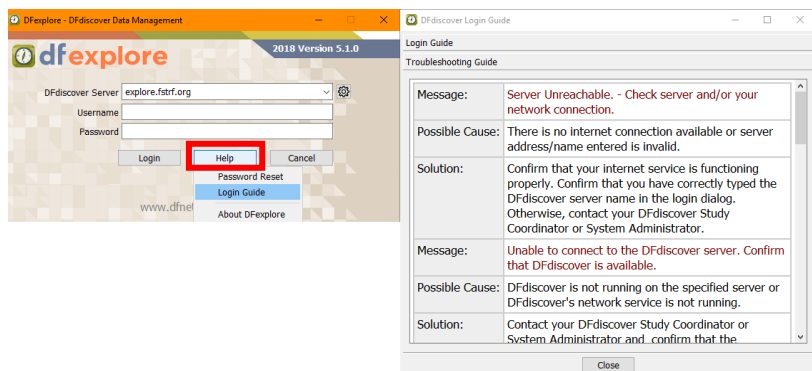


NOTE regarding Proxy Server: If your IT department has installed a proxy server (to filter requests sent to other servers on the internet) click the gear button to the right of the ' DFExplore Server' name to register the proxy server. You may need to contact your IT department for the necessary information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

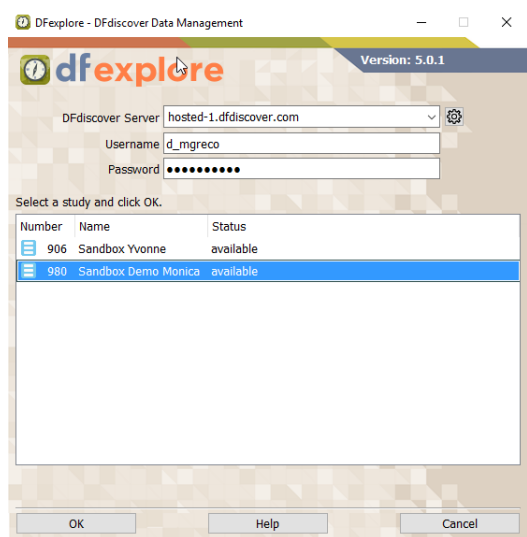


However, if you do not use a proxy server, you should connect directly to our DF server at explore.fstrf.org and should leave the gear button dialog box empty.

The Login box contains a Help button for troubleshooting:



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



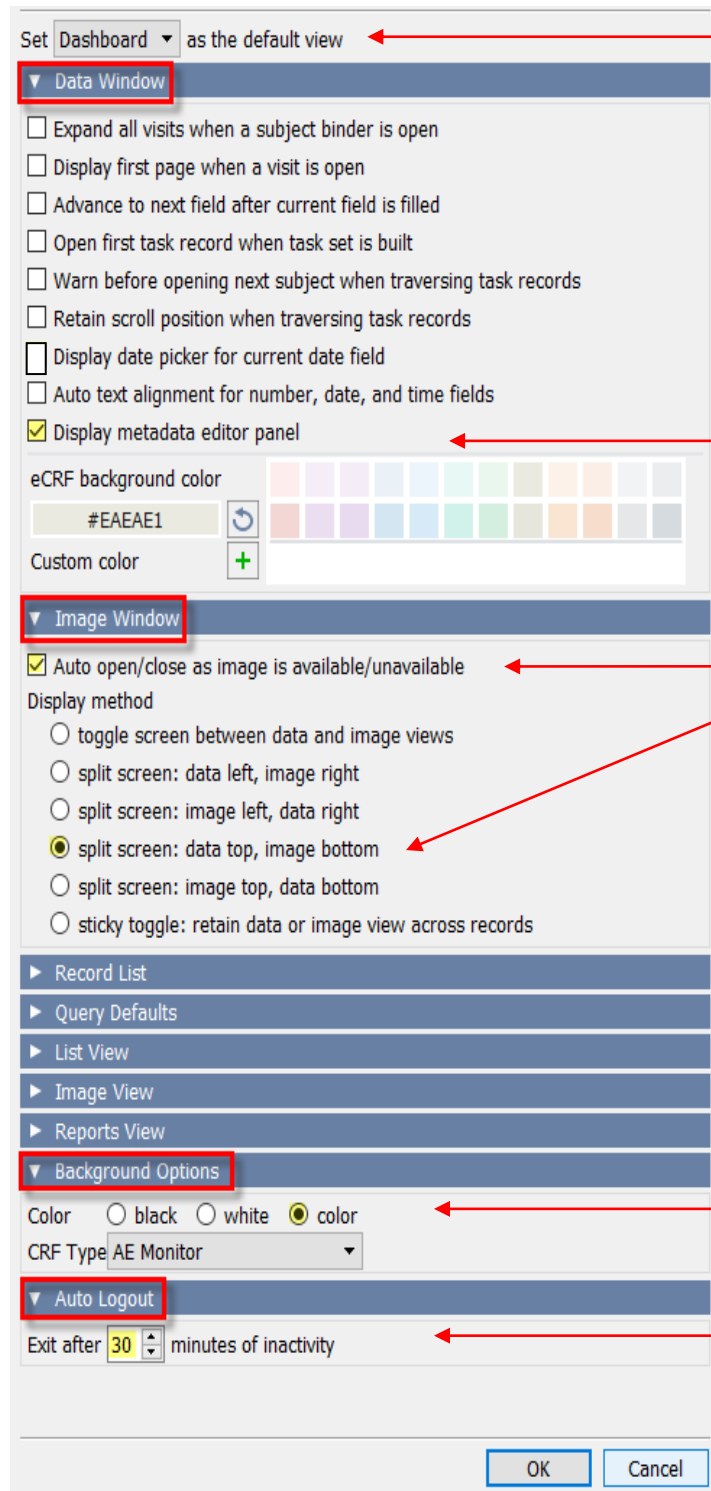
4. Double click the appropriate trial or select a trial and click on 'OK' or select the trial and press enter on the keyboard.

Preferences

Once logged in, DFExplore has a number of options to view and navigate through the data. To view the options, select "File" then "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.

Preferences Window suggested settings:



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

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.

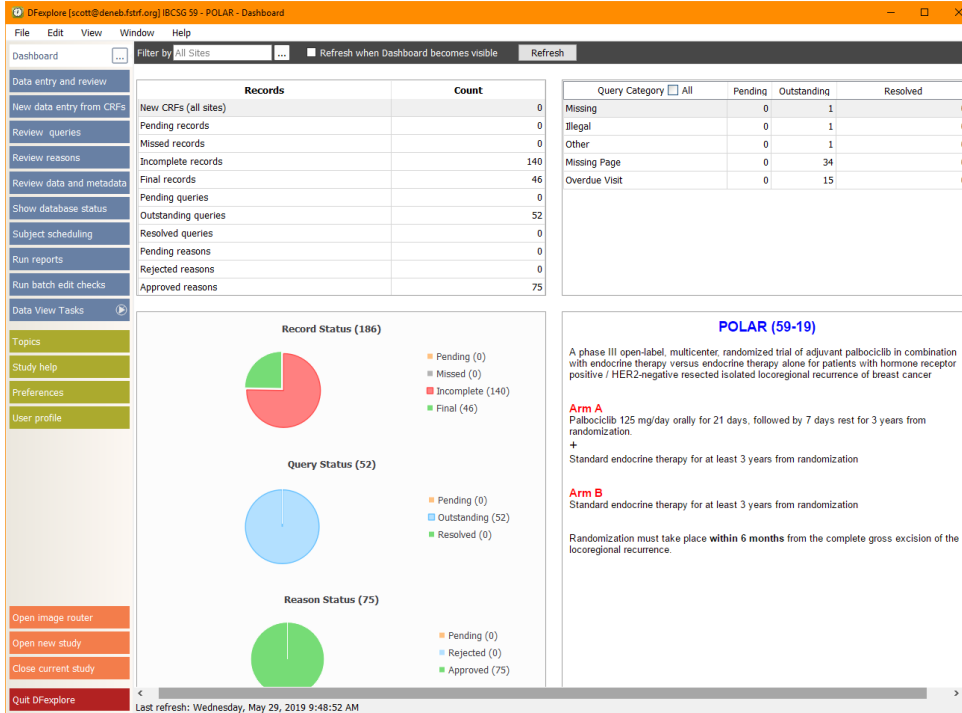
Auto open/close and split screen: data top, image bottom: This allows DFExplore to display the image of any faxed CRF at the bottom of the screen and the data entered in the database at the top of the screen, so both are visible at the same time. If there is no fax image, you see the database on the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

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

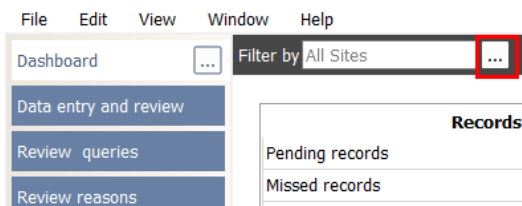
Auto Logout: This is set, by default, to 5 minutes. You can choose an auto logout time up to 30 minutes.

Dashboard View

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



By default, the Dashboard shows metrics for all sites on a selected trial for which you have access. To change the Dashboard to reflect a single site, or a subset of sites, click on the Filter ellipsis and choose the sites you wish to see:



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

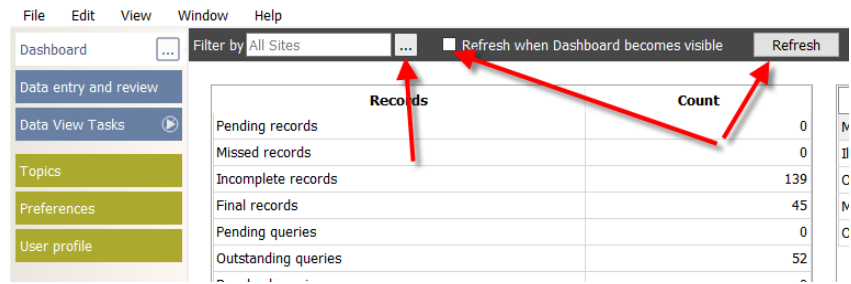
Status Summary - Presented in tabular and chart format, the status summary is an overview of the records and metadata in the current database.

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, illegal, etc.) and statuses (pending, outstanding, and resolved) are columns. By default, categories (and 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.

The Dashboard is interactive and can be refreshed at any time. If you would like to have the dashboard refresh every time you view the dashboard there is a box you can check next to the refresh button (see image below).



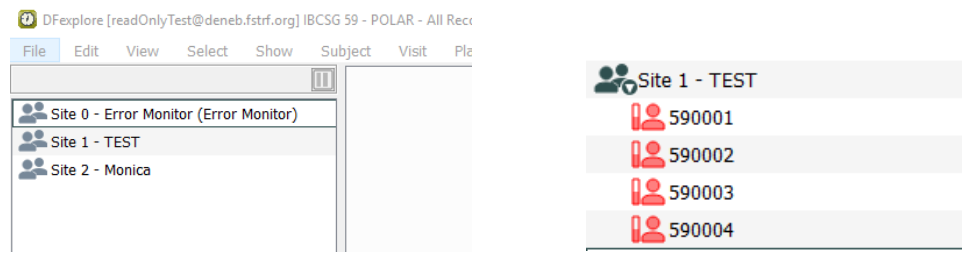
Filter by Center- Above the table of records, there is an option to filter by sites. Click on the box to select a Center from the list. Select a Center and press OK.

Viewing Data

To View Center data, select “Data entry and review” from the tabs on the left side of the Dashboard View. You will then see a list of Centers (referred to as ‘Sites’ in DFExplore). Double click the Center to bring up a list of patients enrolled under that Center. Double click on the patient icon to open the patient binder. Inside the binder is a list of all forms for the patient. If your Group is a Coordinating Group, you see all Centers (and patients) from your Group. When you are finished viewing data, double click on the visit or patient icon to close.

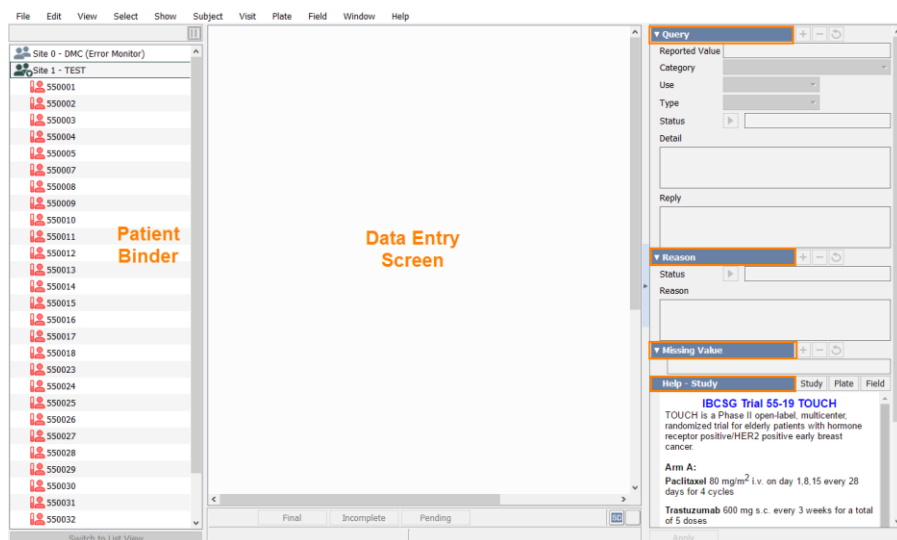
Centers are listed in the order they entered the trial. Site Number (if shown) is the DFExplore Number for that particular Center in this trial.

Within 24 hours of patient randomization via the IBCSG Registration/Randomization system, the patient binder will appear under under the appropriate Center listing in DFExplore.



Navigating through DFExplore

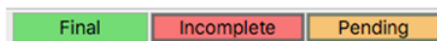
The DFExplore data screen consist of six sections (Center/Patient binder, Data screen, Query box, Reason box, Missing value box, and Help box):



Patient Binder

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

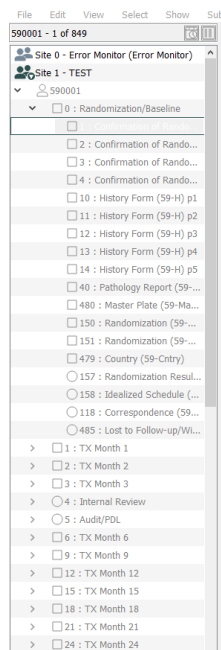
The subject binder colors and icons correspond to the page Save status:



Subject icons:

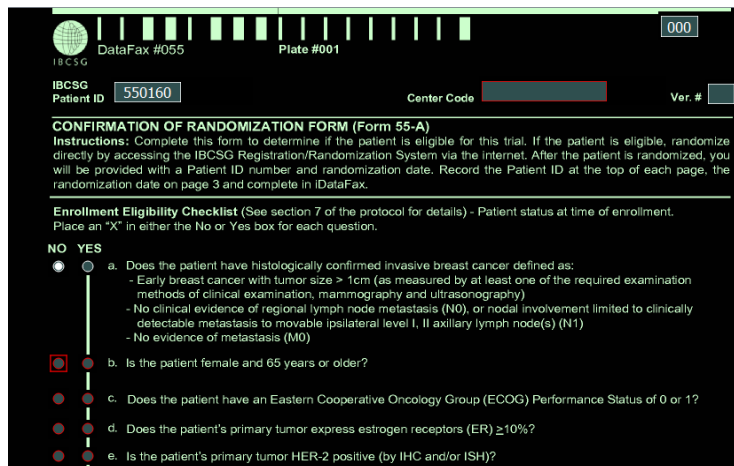
	Green, filled scale	No problems, all pages with status final
	Red, half-filled scale	At least one page with status incomplete
	Orange, outline scale	At least one page status pending, none incomplete
	Grey, dashed outline scale	All pages marked missed (i.e. unavailable)

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



Data Screen

Data is entered on these screens by the Center. 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:



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 and understanding 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

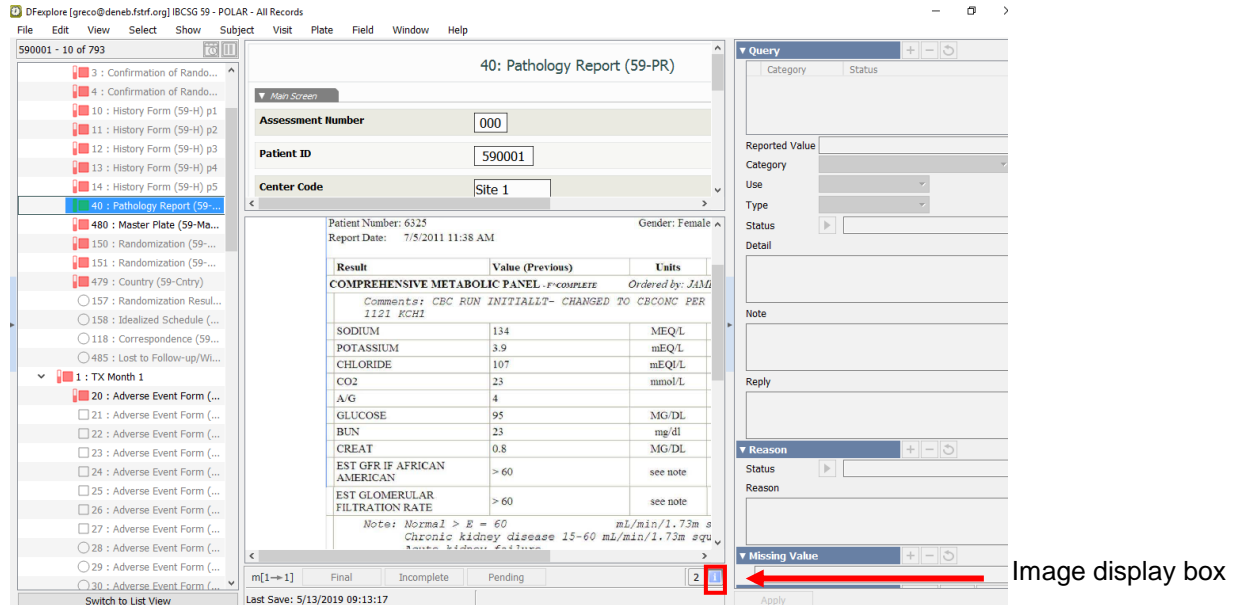
1a. Besides this form, which CRFs were completed for this unscheduled visit? (Mark all that apply or "None")

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 can not be seen, select the toggle display box  at the bottom right of the data entry window.



40: Pathology Report (59-PR)

Assessment Number: 000
Patient ID: 590001
Center Code: Site 1

Patient Number: 6325
Report Date: 7/5/2011 11:38 AM
Gender: Female

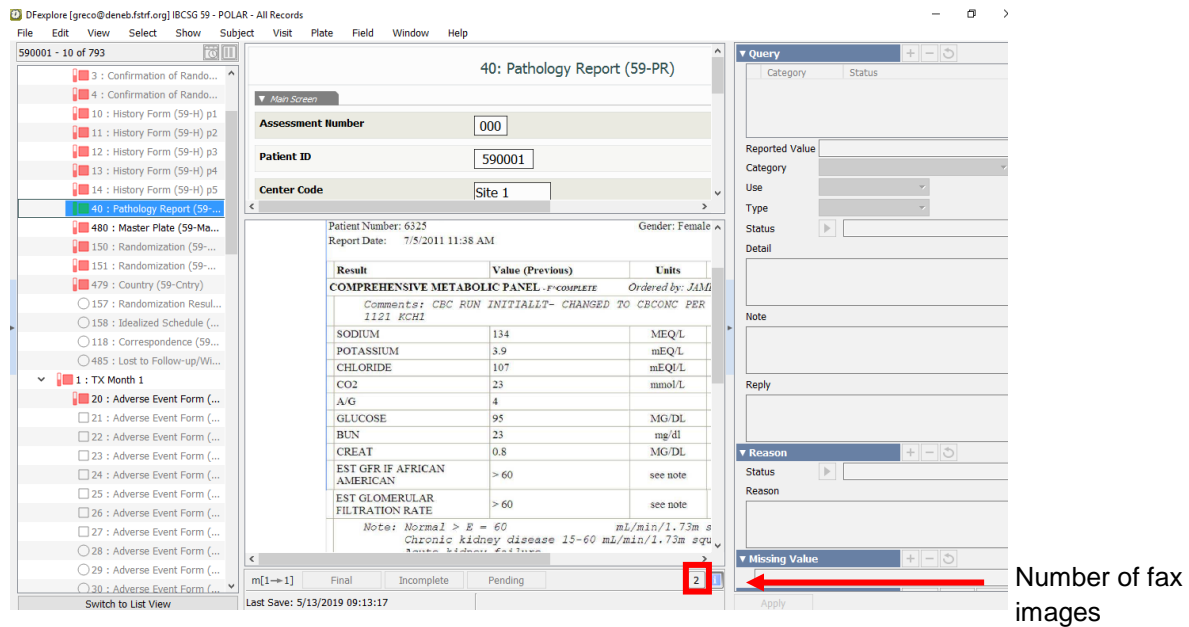
Result	Value (Previous)	Units
COMPREHENSIVE METABOLIC PANEL - P-COMplete Ordered by: JAM		
Comments: CBC RUN INITIALLT- CHANGED TO CBCOMC PER 1121 KCHI		
SODIUM	134	MEQ/L
POTASSIUM	3.9	mEQ/L
CHLORIDE	107	mEQ/L
CO2	23	mmol/L
A/G	4	
GLUCOSE	95	MG/DL
BUN	23	mg/dl
CREAT	0.8	MG/DL
EST GFR IF AFRICAN AMERICAN	> 60	see note
EST GLOMERULAR FILTRATION RATE	> 60	see note

Note: Normal > E = 60 mL/min/1.73m²
Chronic kidney disease 15-60 mL/min/1.73m² squ

m[1=>1] Final Incomplete Pending **1**

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.



40: Pathology Report (59-PR)

Assessment Number: 000
Patient ID: 590001
Center Code: Site 1

Patient Number: 6325
Report Date: 7/5/2011 11:38 AM
Gender: Female

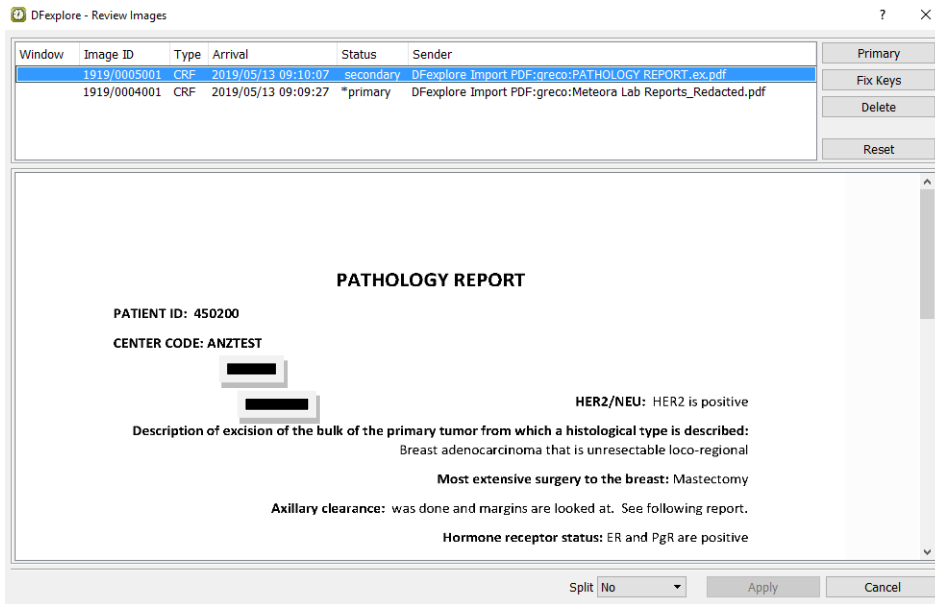
Result	Value (Previous)	Units
COMPREHENSIVE METABOLIC PANEL - P-COMplete Ordered by: JAM		
Comments: CBC RUN INITIALLT- CHANGED TO CBCOMC PER 1121 KCHI		
SODIUM	134	MEQ/L
POTASSIUM	3.9	mEQ/L
CHLORIDE	107	mEQ/L
CO2	23	mmol/L
A/G	4	
GLUCOSE	95	MG/DL
BUN	23	mg/dl
CREAT	0.8	MG/DL
EST GFR IF AFRICAN AMERICAN	> 60	see note
EST GLOMERULAR FILTRATION RATE	> 60	see note

Note: Normal > E = 60 mL/min/1.73m²
Chronic kidney disease 15-60 mL/min/1.73m² squ

m[1=>1] Final Incomplete Pending **2**

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) by the Center.

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 used by the Center.

Missing Value Window

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

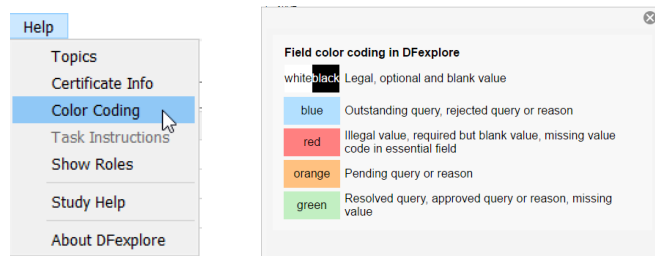
Help-Study Window

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

Color Coding

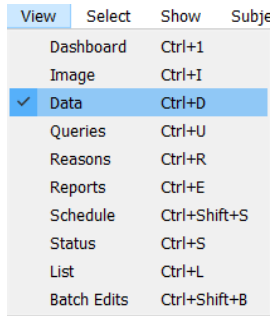
DfExplore uses different colors to provide information about each field. The chart below explains each color that is used in DfExplore.

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

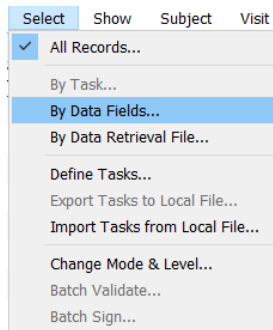


Selecting Centers in iDataFax

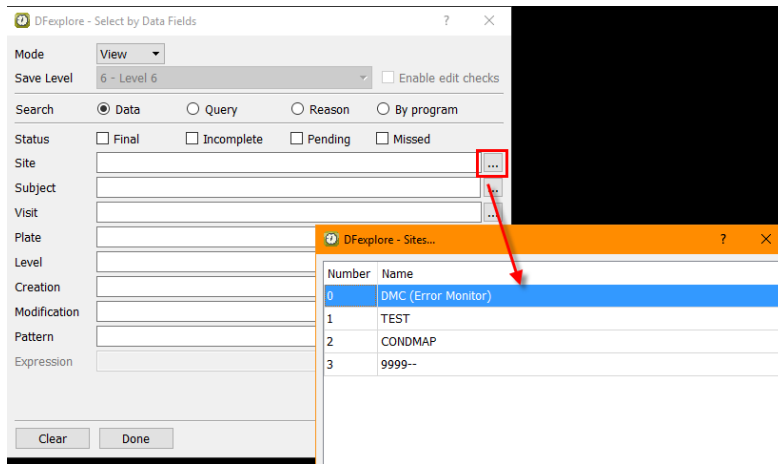
1. To obtain a set of data for one specific Center, select View → Data from the toolbar.



2. Then click on Select → By Data Fields from the toolbar to bring up a dialogue box.



3. Click on the “...” button to the right of the “Site” field to bring up a list of all Centers for which you have access.

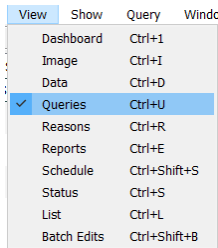


4. To sort by the Center Code in alpha-numeric order, click on the “Name” title at the top of the box.
5. Select the Center Code you would like to view, and click the “Apply” button. The DFExplore Center number will appear in the “Site” box.
6. Click the “Build Set” button and then “OK” to obtain a set of data containing all the patients for that Center.

Accessing Queries

To create a list of all outstanding queries:

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



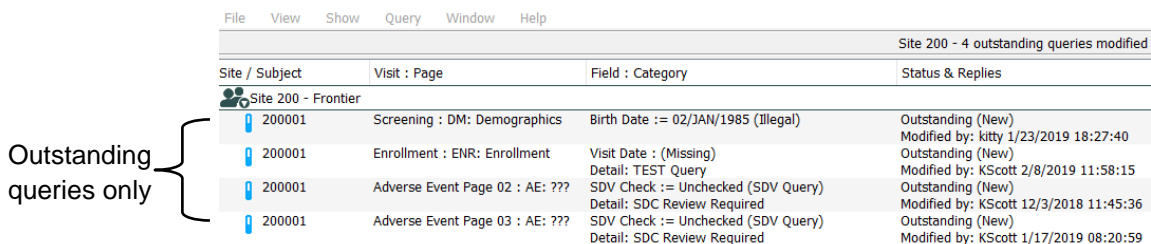
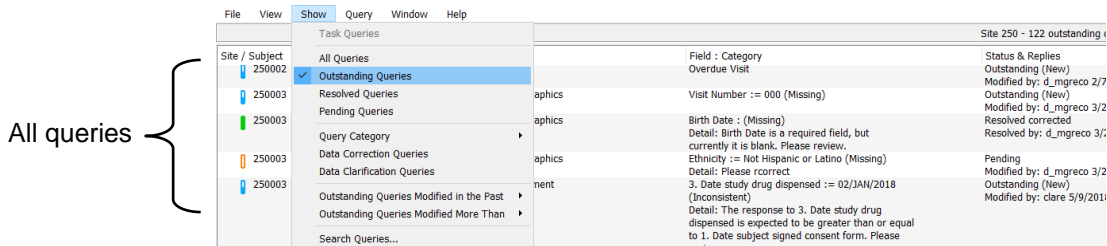
3. Alternatively, queries may be selected from the Dashboard View in one of two ways:

The screenshot shows the 'Data entry and review' dashboard. On the left, a sidebar menu has 'Review queries' highlighted. The main area contains a table with columns 'Records' and 'Count'. The 'Outstanding queries' row is highlighted. To the right, a summary table shows counts for 'Pending' and 'Outstanding' queries across various categories.

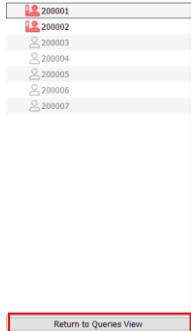
Records	Count
Pending records	2
Missed records	0
Incomplete records	286
Final records	170
Pending queries	3
Outstanding queries	1568
Resolved queries	0

Query Category	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

- 3.1. Clicking on the “Outstanding” queries column takes you to the individual queries on the data field.
- 3.2. Using View → Queries or clicking on “Review Queries” on the left, shows queries as follows:
 - A list of all queries for all 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 the Center. Pending queries are indicated with an orange icon. These are awaiting DMC approval.
 - You can narrow the list of queries are displayed (e.g., all queries, only outstanding ones, etc.) by selecting the “Show” drop down menu on the tool bar.
 - Select the desired option.



4. Double click on an individual query line to open the patient binder to the CRF page that has the query and the field where the query is placed.
5. To return back to Query View, click on the “Return to Query View” bar located below the patient binder.



6. When you are done with Query View, you can return to the patient binder by selecting View → Data.

QC Reports

Quality Control Reports are distributed on a regular basis via email. The QC report should be sent to the Center. 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 Centers have a chance to answer them before the next QC Report is generated.

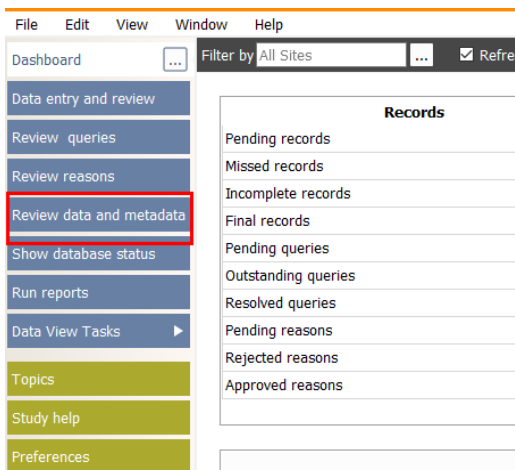
For older trials, Centers' outstanding queries may also be sent. Centers can either answer the queries on paper and send the response back via DFsend or fax, or answer the queries directly in DFExplore.

Centers do not need to do both.

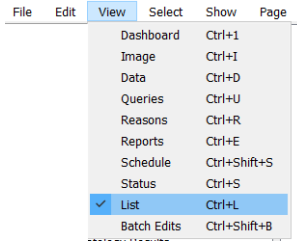
List View

List View allows you to view data records for a selected CRF page in spreadsheet form for all 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.



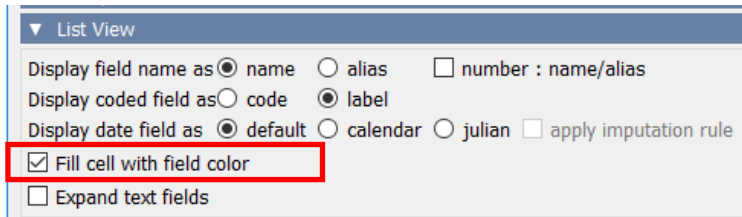
When one page is selected, a table replaces the data window. The table lists each field on the page and the data entered in DExplore for each patient.

The screenshot shows the application window with a table of patient data. The table has columns: DFSTATUS, DFVALID, DFRASTER, DFSTUDY, DFPLATE, VISITNUM, SUBJID, VISDAT, MHSPID, MHTERM, MHSTDAT, and MHENDAT. The table contains 10 rows of data for various patients, with some cells highlighted in red or green.

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	

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

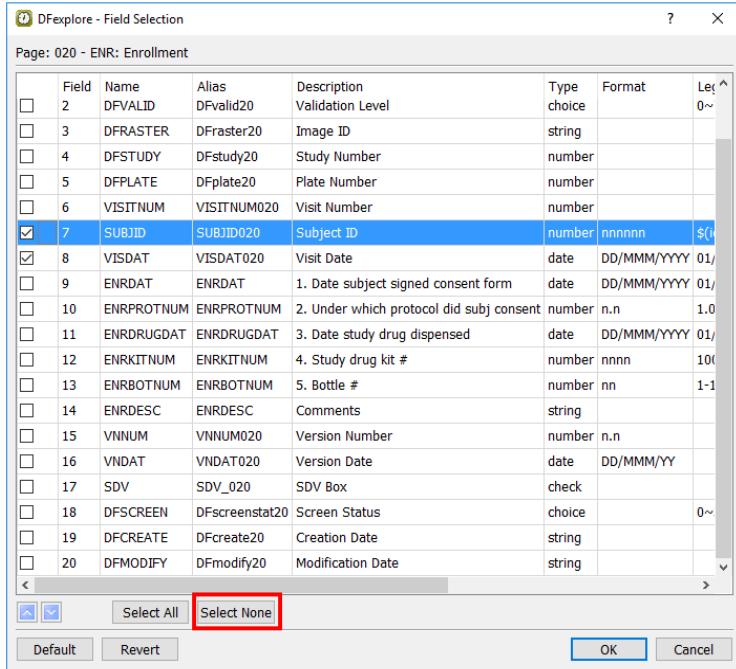
The fields can also be color-coded to match the data (blue for fields with queries, green for resolved field, etc.). To activate this option, choose “File” from the tool bar and “Preferences” from the drop-down menu. Under “List View” click on “Fill cell with field color” and then click “OK”.



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.

1. Click on “Select None” and then individually select the fields you want to review.

2. Click “OK”. The screen shows only the fields you selected.

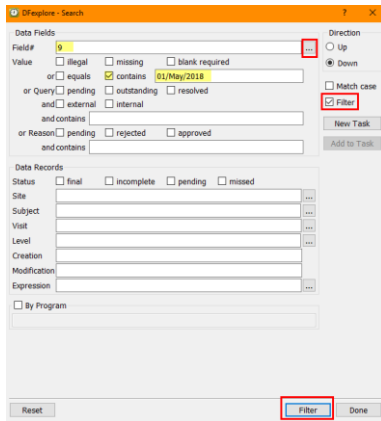


Searching a Field in List View

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 selected records appear in the window.

The screenshot shows the DFExplore interface. On the left, there is a sidebar menu with 'Plates & Metadata' and 'Modules' tabs. Under 'Modules', there are options for '001 - DM: Demographics', '010 - IE: Inclusion Exclusion', and '020 - ENR: Enrollment', with '020 - ENR: Enrollment' selected. The main window displays a table with the following columns: DFSTATUS, DFVALID, DFRASTER, DFSTUDY, DFPLATE, VISITNUM, SUBJID, VISDAT, and ENRDAT. Two records are visible:

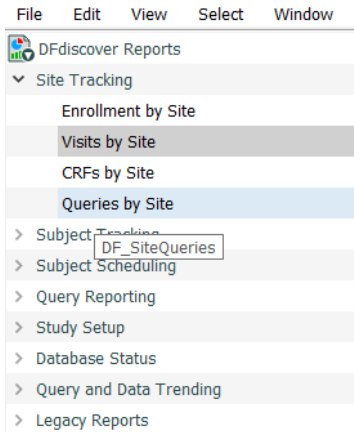
	DFSTATUS	DFVALID	DFRASTER	DFSTUDY	DFPLATE	VISITNUM	SUBJID	VISDAT	ENRDAT
1	final	1st Pass Entry	1819R002P020	30	20	001	250007	01/MAY/2018	01/MAY/2018
2	final	1st Pass Entry	1819R003H066	30	20	001	450007	01/MAY/2018	01/MAY/2018

Reports

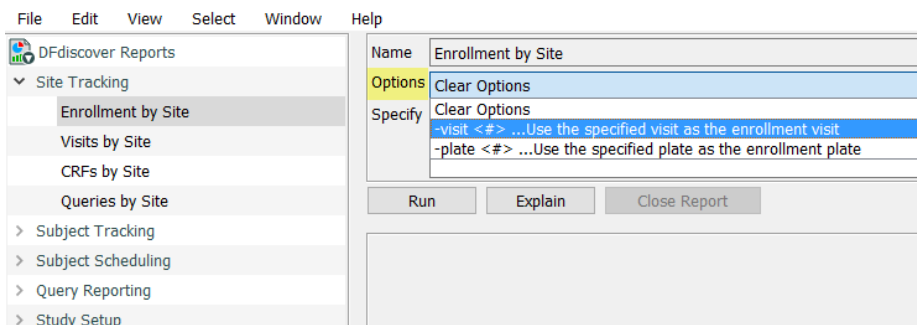
DFExplore has many reports that aid in understanding the data in DFExplore (compliance, accrual, etc.).

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

NOTE: 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.

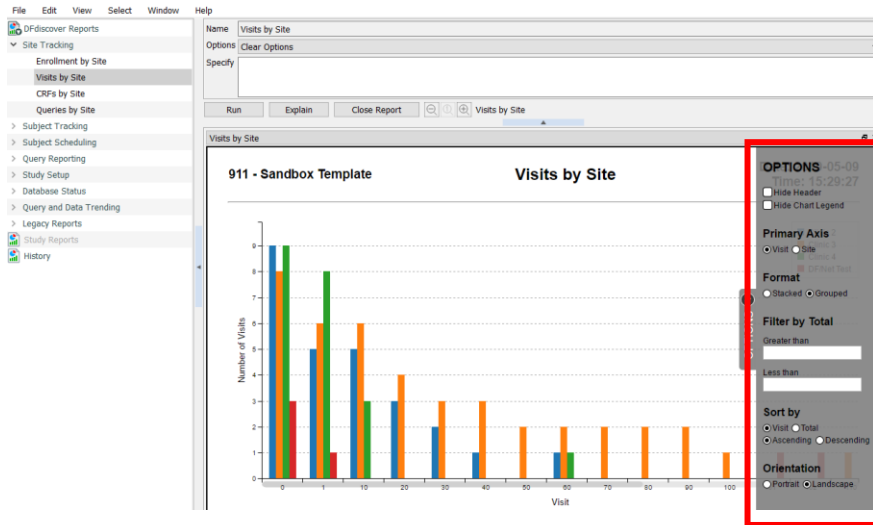
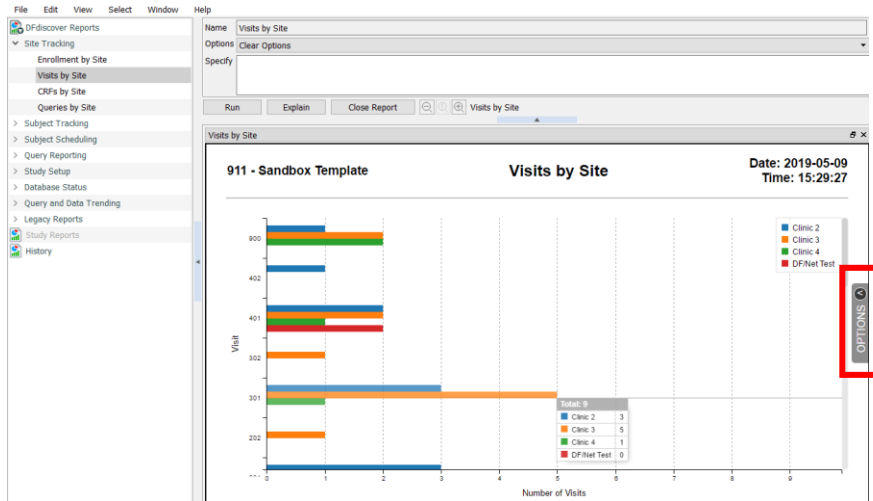


Click on a report option. From the drop down, select the data options to specify in the report. Click “Run”.



The reports are interactive and clickable output can be manipulated and displayed in different ways without re-executing the report. They can be pulled off the DFExplore screen (click on the report and drag it off DFExplore 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.

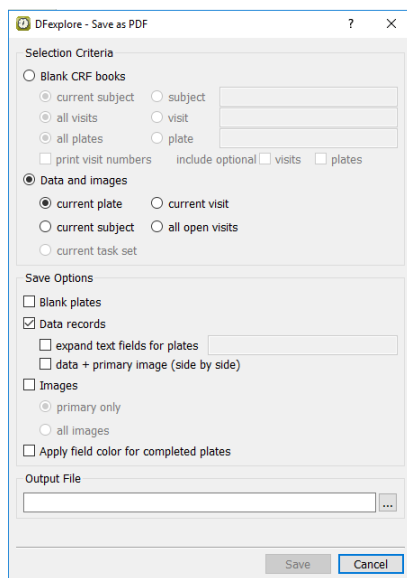
Saving Data from DFExplore

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 above for descriptions of most of the options)
5. 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 options 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.

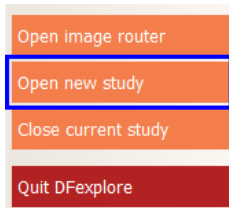
- **Data records:** Prints pages with data. The data and primary (data submitted by DFsend or fax) images can be printed side by side.
- **Images:** Prints any images submitted by DFsend or Fax. If more than 1 image is held on the same page, one image is assigned as primary and all others are secondary. If you want to print all images for that page, select “all images”.
- **Apply Field 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”.

Switching Between Trials

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

1. Select “File”.
2. 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”

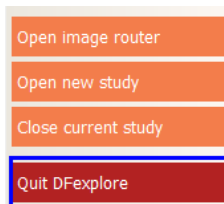


3. This displays the initial Lists of Trials. You can now open another DFExplore trial by double clicking on that trial.

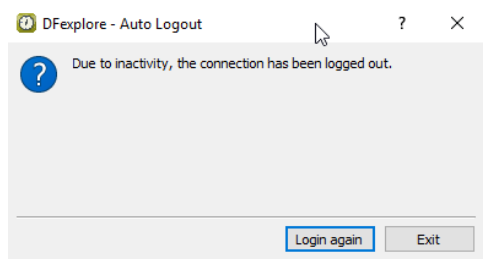
NOTE: You can have more than one trial or multiple instances of the same trial open at the same time in DFExplore. Multiple sessions of DFExplore can be opened to look at different patients.

Logging Out of DFExplore

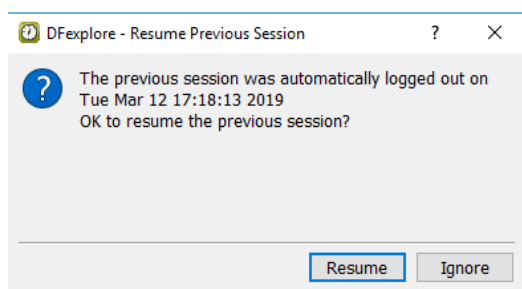
1. Select “File”.
2. Select “Exit”.
3. You can also log out from the Dashboard View by clicking the “Quit DFExplore” tab on the bottom left:



4. 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.”



5. 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 you do not want to return to the last page click “Ignore”.



DFsend

Some information cannot be entered electronically in DFExplore by the Center. 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

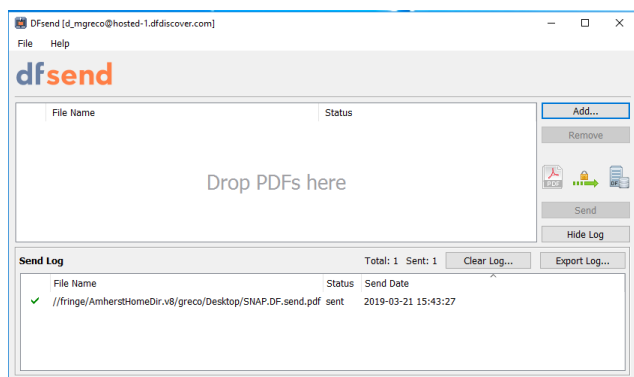
Be sure you have downloaded DFsend from <https://www.ibcsqdmc.org/ibcsq/df/downloads.view> .

NOTE: 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.ibcsqdmc.org/ibcsq/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.

3. 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.
4. Transmit - Click the Send button to send the selected PDFs to the study server. Enter your username and password again for verification.
5. 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.



6. 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".

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@fstf.org or via phone at +716-834-0900 ext 7302.