IBCSG

International Breast Cancer Study Group

DFexplore Study Monitor Instructions for Source Data Verification (SDV)

Version 7.0

May 2022

IBCSG Data Management Center

DFexplore Study Monitor Instructions for Source Data Verification

Note: Familiarity with DFexplore is a prerequisite for the procedures in this manual.

Definitions/Acronyms/Abbreviations

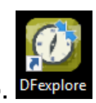
Term/Acronym	Definition
CRF	Case Report Form
DM	IBCSG Data Manager
DMC	IBCSG Data Management Center
DF	DFexplore
SDV	Source Data Verification

Introduction

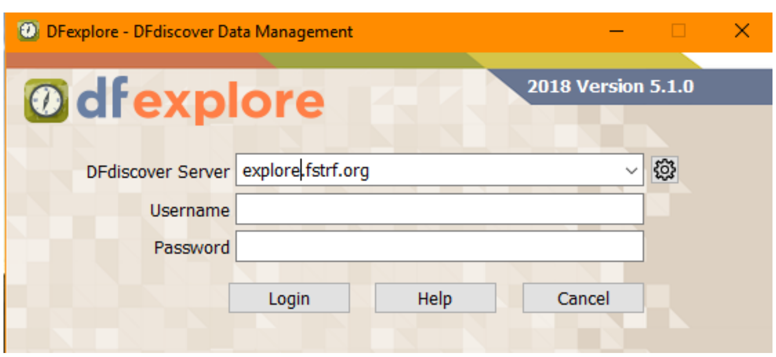
Source Data Verification can be done directly in DFexplore by the monitor. The monitor can view all patient records, monitoring tasks such as SDV, adding and resolving queries at Validation Level 2 or 6.Level 2 refers to data entered by the center that is new or has been amended and is not yet reviewed/managed by the DMC Level 6reflects the record has been reviewed and managed by the DMC.

The Data Management Center makes every effort to keep all records at Level 6 in real-time. It is recommended monitors inform the Data Management Center 1-2 weeks prior to when they plan to monitor a Center so all data can be as clean as possible and at Validation Level 6. The DMC will inform the monitor of any issues that should be addressed at the visit.   Monitors can also enter Protocol deviations on the Patient Deviation Log if they have not yet been reported.

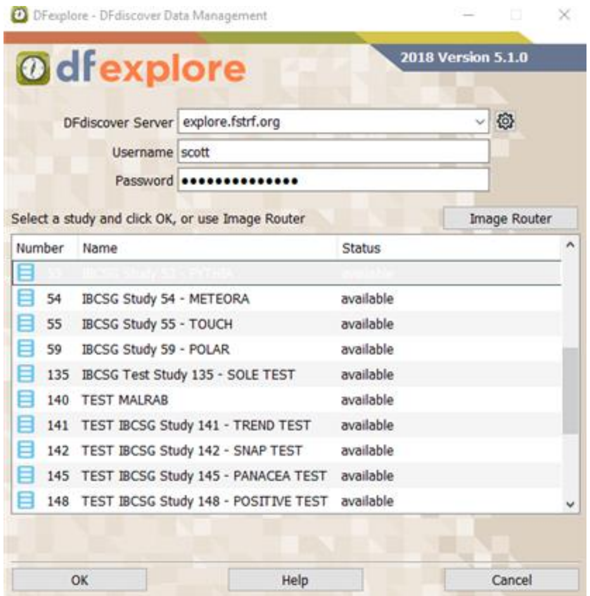
Starting DFexplore

1. To connect to DFexplore, double-click the DFexplore icon on your desktop. 

2. In the Login box, verify the DFdiscover Server field displays “explore.fstrf.org”. If not, type it in.
3. Enter your User Name and Password.



4. Click “Login.” A list of trials to which you have access is displayed.



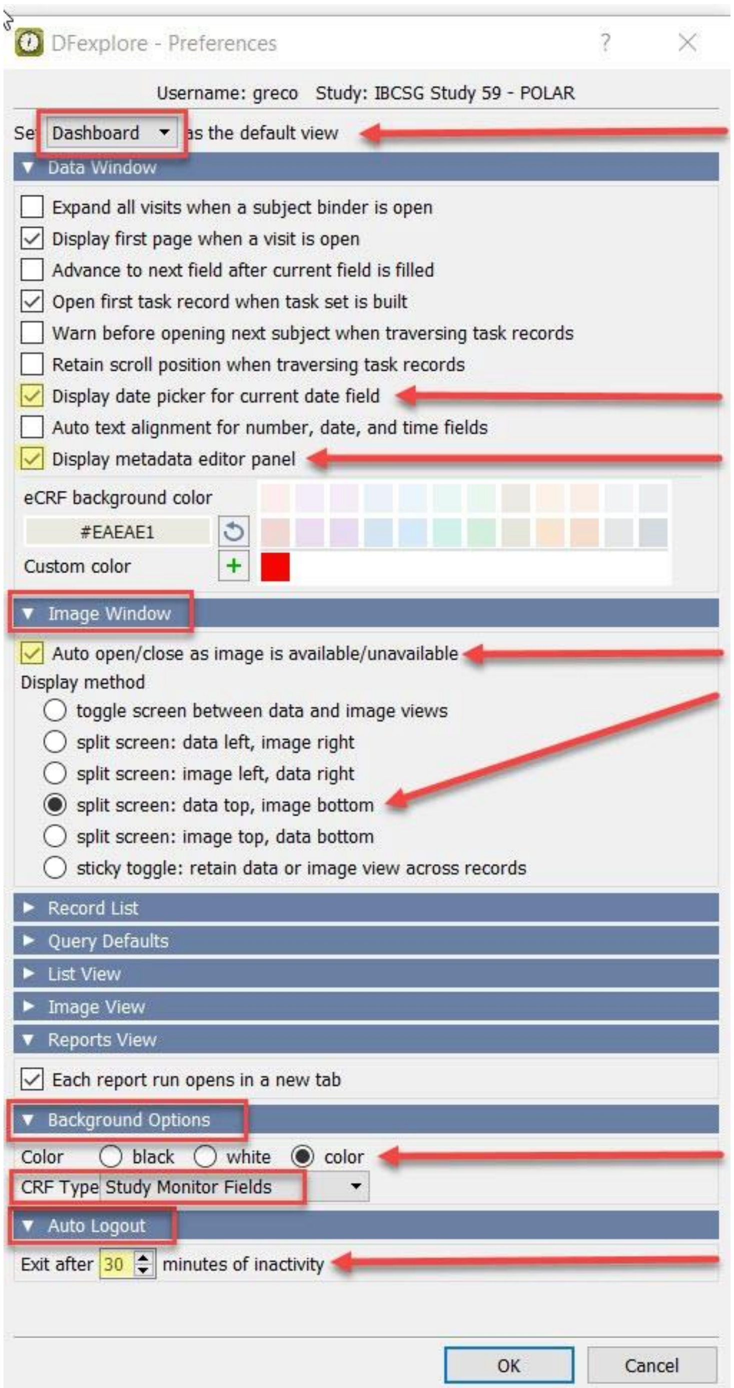
5. Double click the appropriate trial or select a trial and click on ‘OK”.

Preferences

Once logged in, DFexplore 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.

Suggested settings (for Trials 41 and up):



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 displays a calendar icon next to date fields so you can select a date.

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: Select this for 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 available, the database is displayed full screen.

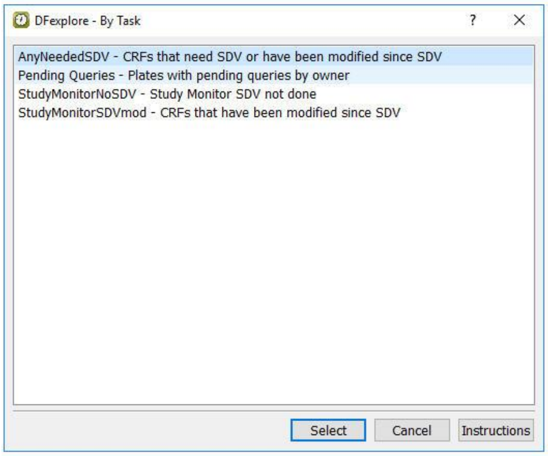
Color: This enables the color features in DFexplore. For older trials (55 and below), you may want to select black or white for the background.

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

Select a Task

1. After logging in to DFexplore, be sure you are in Data View. (Select “View” from the Toolbar and then “Data”.) Build a set of records to be source data verified by using one of the four pre-defined tasks.

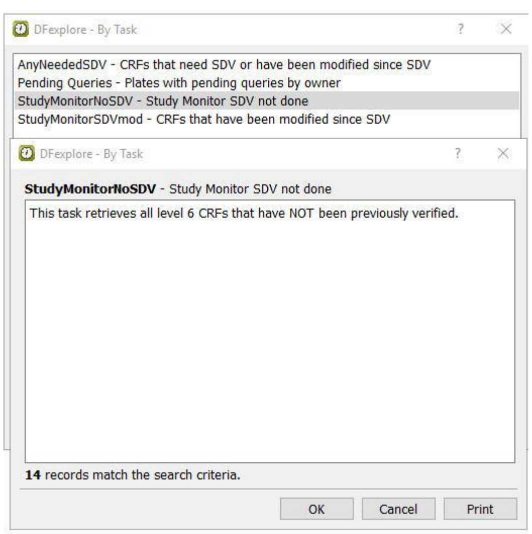
2. Click on “Select” in the tool bar and then “By Task…” in the drop down menu. The “DFexplore- By Task” window is displayed.



Four tasks are available:

- AnyNeededSDV – CRFs that need SDV or have been modified since SDV. This task builds a set of CRFs that have not yet been SDV or have been modified since SDV.
- Pending Queries - Plates with pending queries created by the user.
- StudyMonidorNoSDV – Study Monitor SDV not done. This task retrieves all CRFs that have NOT been previously verified.
- StudyMonitorSDVmod – CRFs that have been modified since SDV. This task builds a set of CRFs that have been modified since original SDV.

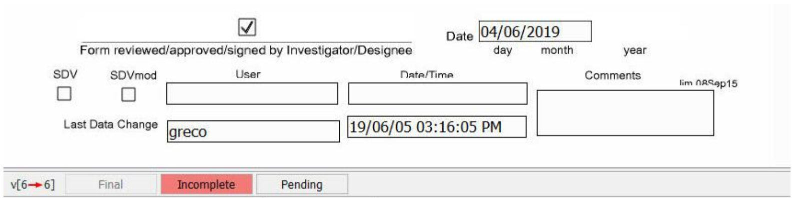
Click the ‘Instructions’ button to display the task descriptions (listed above) to see which records are retrieved for the selected task.



1. Select the task to highlight it.

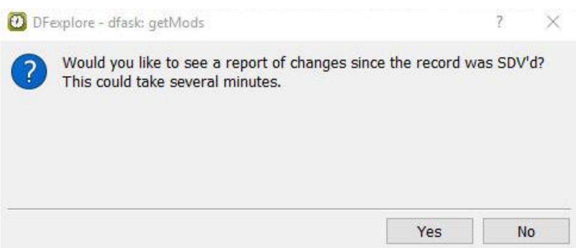
2. Click the “Select” button to retrieve the records, (if any), that match the task criteria.
3. Click “OK” to load the matching records.
   This opens the first patient with a task record. The task record has a grey plus sign to the left of the form name. Completing the task and saving the page causes the grey plus sign to become a red or green checkmark. This is a visual cue to show the stage of your task records.
4. To view all records for the patient, click on “Show all records for this subject” button below the patient records.
5. To return to viewing only your task records, click the button again.

The bottom of each CRF contains the SDV fields. Centers do not see these fields. These fields, along with the rest of the data fields are not editable by Study Monitors, EXCEPT for the Comments field. The Comments field is for monitor use only and should not be used to address the DMC. DMs do not review anything written in this field.



Viewing Changes to Records That Have Been Modified Since Last SDV

If a record is pulled up that has been modified since last SDV, a pop-up window asks if you would like to see the changes that have been made.



If you click “Yes”, an internal audit trail of that record is run and the changes are displayed in a dialogue box.

Click “Print” if a hard copy is needed.

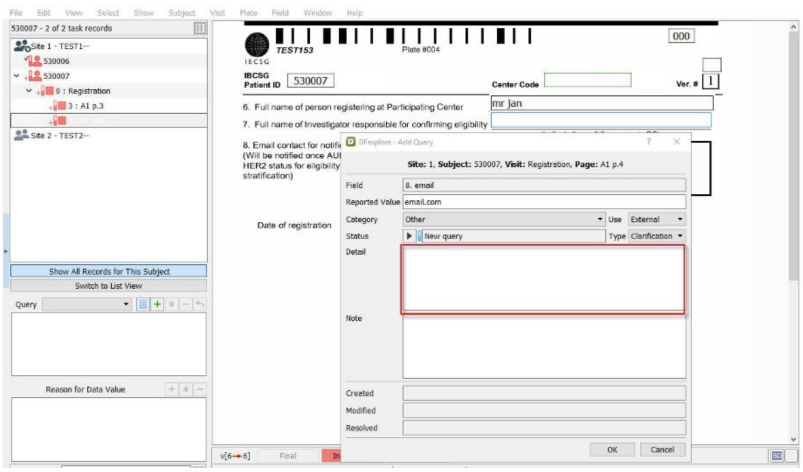
Add a Query

Study Monitors can add a query to any field on a record if needed for SDV.

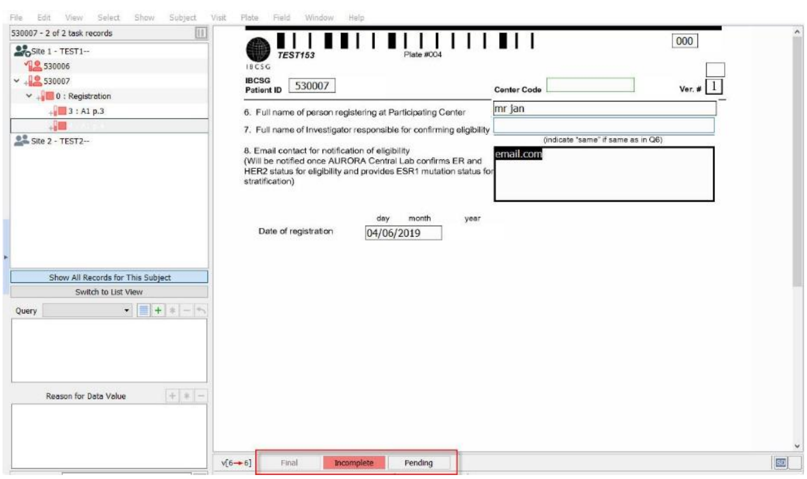
1. Select the field that requires a query. Click on “Field” in the tool bar and then select “Add Query…”
2. Enter text details in the Details section and click “OK”. Other default values can be left as is (be sure *Use* is set to “External” and *Type* is set to “Clarification”).

   For studies prior to 59-19 (POLAR): Only one query can be added to a field. If there is already a query on a field (the field is blue), another query cannot be added to it regardless if the first query was added by a Study Monitor or a Data Manager. In this case, you need to add a query on another relevant field.

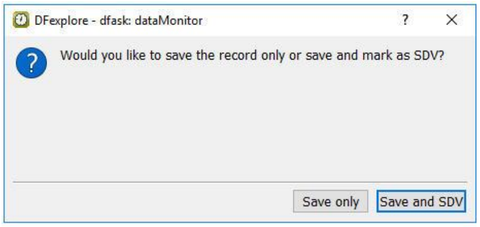
   The 59-19 POLAR Trial can have multiple queries on a field. Multiple queries on a field are denoted with a number next to the query.



3. To save the record, click on “Final” (no outstanding queries) or “Incomplete” (queries outstanding; noted as blue fields). If there are red fields, these are required fields that are missing and the record must be saved as “Incomplete”. It cannot be able to be saved as “Final” until these fields are completed. **You are able to save the record as “Pending”, but please do not use this option.**



4. You have the option to either save the record or to save it and mark is as SDV. A pop-up offers these options:



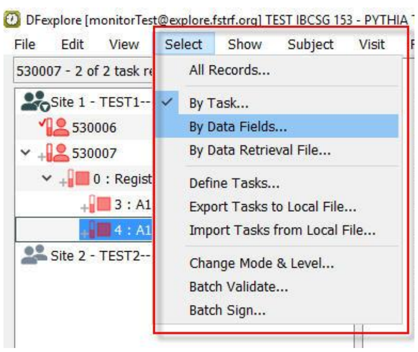
If you have added a query, you may want to choose to only save the record until a reply is received. Once the query is answered, you should then choose to SDV the record.

Retrieve All Data Records

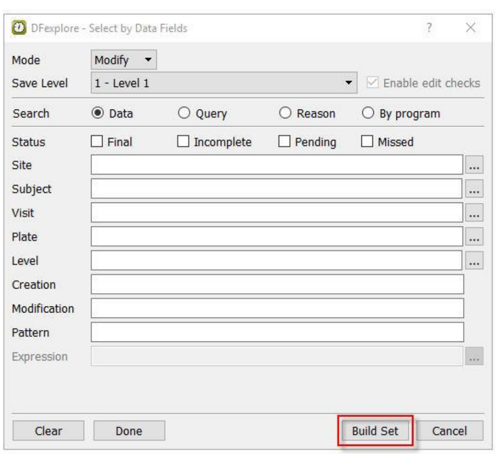
Using the Task Set above does not allow the monitor to view or print all records for a patient. It shows only the Task Set selected. Occasionally, all data may need to be retrieved.

Note: No monitor tasks should be done when retrieving the whole patient record. All monitor tasks must be done using the Task Set.

1. To obtain a set of all records for a patient, click on “Select” in the tool bar and then “By Data Fields” in the drop down menu.

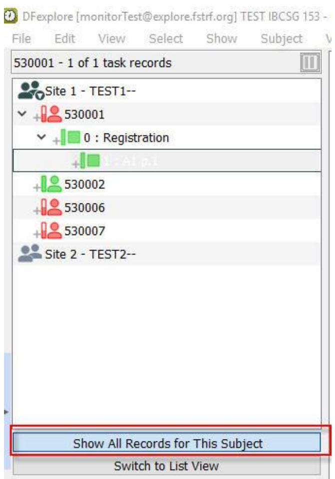


2. Enter text in the fields in the option box to pull up the desired records (Site, Subject, Visits, etc.).
3. Click “Build Set”.



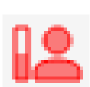
4. A pop-up box is displayed. It indicates how many records match the criteria selected. Select “OK” to display the requested records.

5. Once selected, the display on the left changes. The records matching the chosen criteria are displayed.



6. To view the entire patient binder (CRFs with data and CRFs that have not yet been completed), click on “Show All Records for This Patient” (see red box above). This pulls up the entire patient binder, which is a list of every form for the trial. Completed CRFs are bolded while those with no data are grayed-out.


This icon next to the patient ID means that all required data are in, with no outstanding queries or unapproved reasons for change.


This icon next to the patient ID means that there are missing forms/pages/required data fields, outstanding queries or rejected reasons for change.

Search for Queries

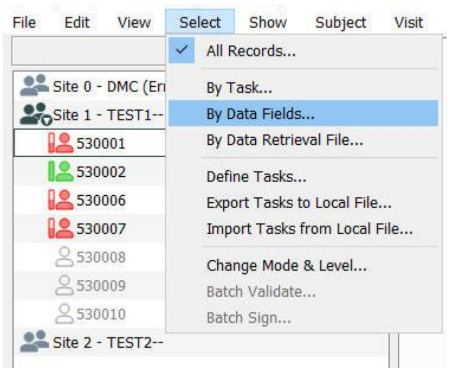
While IBCSG monitors resolve their own queries, other Cooperative Groups have chosen to have the IBCSG DMs do this. At the start of monitor participation in a trial, it must be decided if, as monitors, you want to resolve your pending queries (those answered by the Center), or if you want the IBCSG DMC to do so.

Each monitor can search for their own queries and the various statuses. The statuses are as follows:

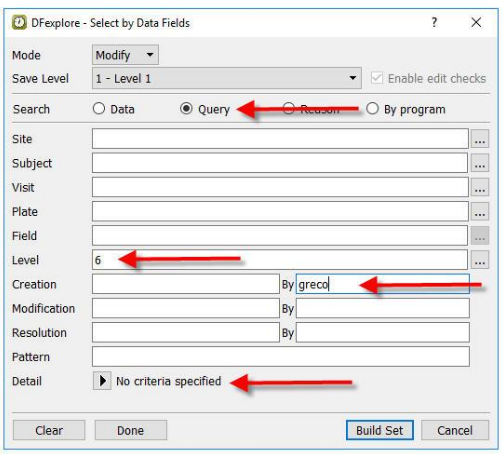
- Unresolved – Query written by the monitor but not yet answered by the Center (field is blue in DFexplore).
- Resolved – Query has been answered by the Center and resolved by the monitor/DMC (field is green in DFexplore).
- Pending – Query answered by the Center, which requires monitor/DMC review and resolution (field is orange in DFexplore).

There is a list of what each color means in DFexplore under the Help Tab.

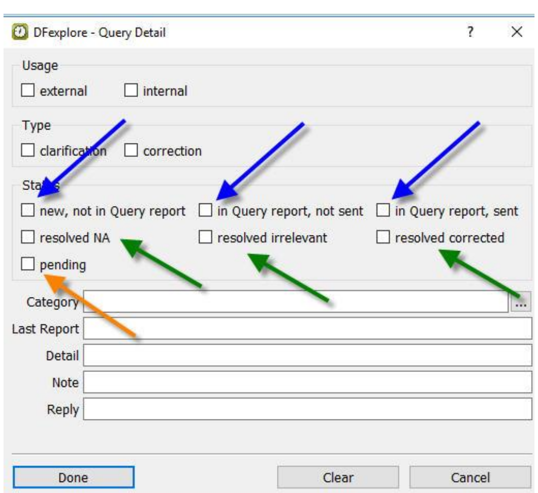
1. Build a set by Data Fields; click on "Select" in the tool bar and then "By Data Fields…" in the drop down menu.



2. Select "Query", Validation Level '6' and put your User name in the "Creation: By" field. Click the "Detail" arrow button.



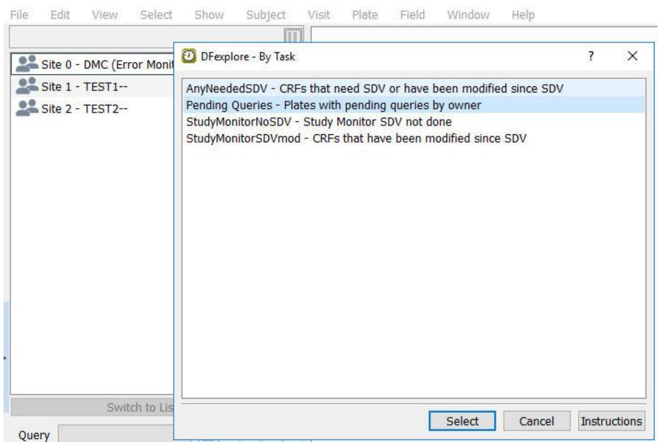
3. The Query Detail box opens. Under Status, choose the "Unresolved", "Resolved" or" Pending" options. Then click "Done".



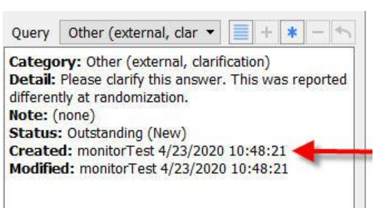
4. The task box closes but the original box remains open. Click “Build Set” and it brings up all the plates that match the selected criteria. Click “OK” and the plates load.

Quick Way to Search for Pending Queries

To resolve queries you have written, that have now been answered by the Center, choose “Select” from the tool bar and then select “By Task”. There is an option called “Pending Queries - Plates with pending queries by owner”. Select this option. This pulls up any records in DFexplore written by the user that have queries with a ‘pending’ status.



These records may also have queries the DMC has written. You may need to review/click on a few queries to find yours. You query has your user name in the Query box, under “Created”.

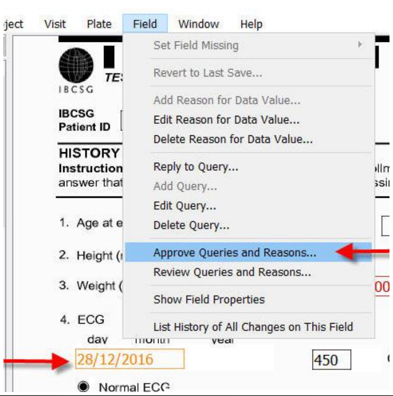


Do not resolve any queries written by the DMC.

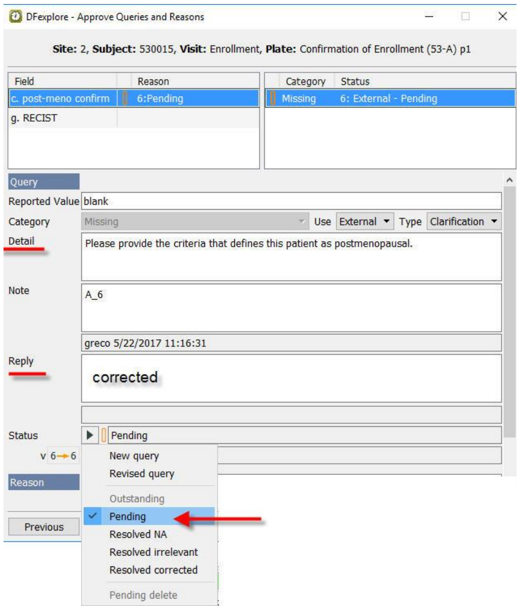
Resolve Pending Queries

Pending queries are those where the Center has replied but the query replies have not yet been approved/resolved by the monitor. These fields with queries are orange in DFexplore.

1. To resolve a query, click on the field with the pending query. Select “Field” in the tool bar, then select “Approve Queries and Reasons”.



2. A dialog box displays showing the query, the Center's reply and the Status of "Pending"



3. To resolve the query, change the status to:
   - Resolved NA – Answer will not be provided
   - Resolved Irrelevant – Query was written in error
   - Resolved Corrected – Answer provided is acceptable
4. There are also options to change the query to a new query or revise the current query. Both options turn the question field back to blue and the Center needs to respond once again.

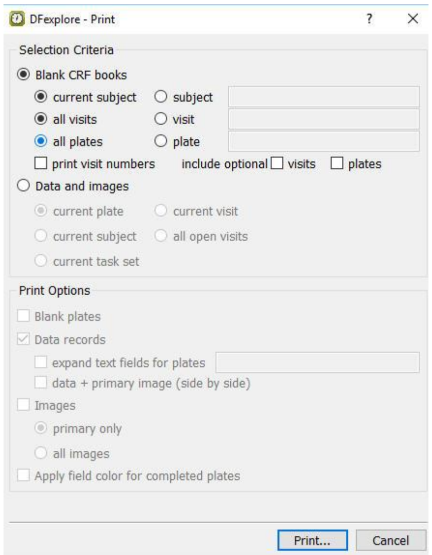
NOTE: As monitors, you have the ability to add and resolve queries, but **you cannot change data**. If the query reply suggests data needs to be changed, but the Center has not changed this data, you must either rewrite the query and instruct them to change the data, or email the DMs at the IBCSG DMC directing them to this query reply so that they can change the data.

Print from DFexplore

You can 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. The Page Setup is displayed. Select the appropriate options.



Selection Criteria - This section allows you to determine how much of the patient binder will be printed:

- Blank CRF books:
  - Current Subject or specific subject
  - All visits or specific visit
  - All plates or specific plate
  - The options to print visit numbers and include optional visits or pates is available
- Data and images:
  - Current Plate: Prints only the page that is open in the data window.
  - Current Visit: Prints all plates in the open current visit
  - Current subject: Prints all pages in the selected patient binder.
  - All Open Visits: Prints all pages in every open visit period (i.e., all CRFs for that visit can be seen). Click the symbol next to each visit period to open it.
  - Current task set: Prints all plates in the current task set that was pulled up.
- Print Options - This section allows you to determine what types of images are printed:
  - Blank pages: Prints a blank copy of the selected pages.

    The PatID and Month Number/Cycle are completed on every printed page, even if “Blank Pages” is selected. Verify that the correct patient binder is selected before printing.
  - Data records: Printed pages include the data entered for that patient. The data and primary images can be printed side by side. The text fields can also be expanded for plates.
  - Images: Prints any faxed images that have been submitted for the patient. You can print a secondary image by selecting “All images” .
- Apply field color for completed plates - Clicking this box applies the colors for each field (e.g., blue for outstanding query, red for required / illegal field, etc.)

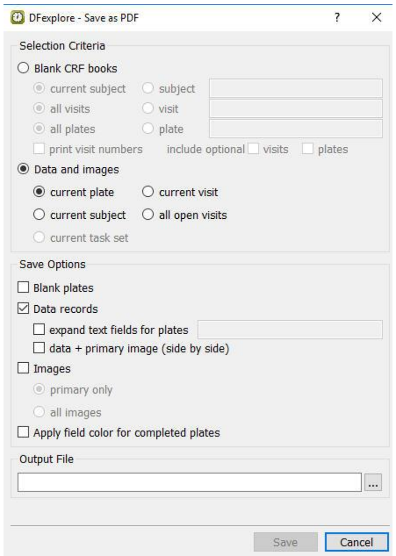
5. Click “Print”.

Saving Data from DFexplore

You can save the patient binder 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. Files saved as PDFs are not viewable by the DMC.

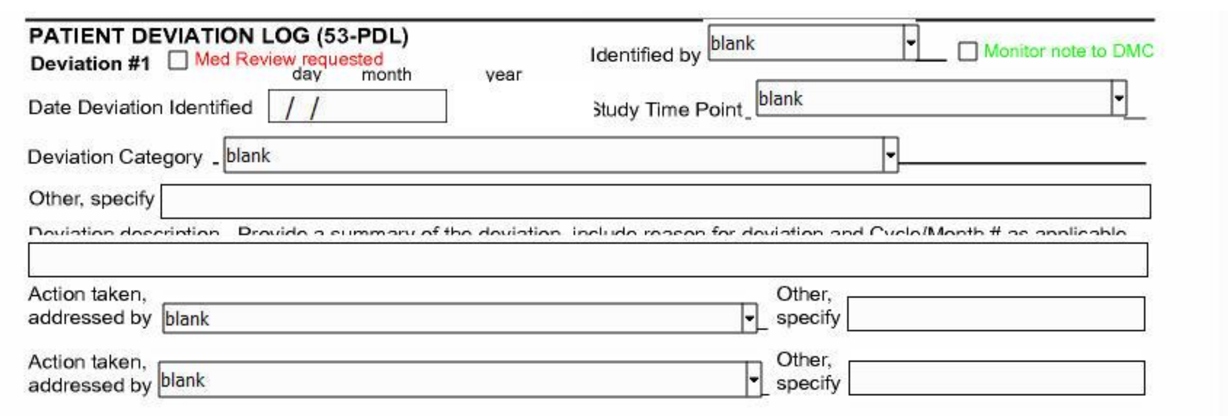
1. Open the appropriate patient binder.
2. Select “File”.
3. Select “Save as PDF”.

4. Choose the options you wish to have in the saved PDF. Options are the same as those used to print the CRFs.



5. The Output File section allows you to assign the name and location of the saved file.
6. Click “Save”.

Patient Deviation Log (PDL)



The PDL is accessible in DFexplore for IBCSG Trials 45 and higher. Monitors, auditors, IBCSG medical review staff, TCs and DMs may edit this form. This is an internal form and it is not available to the Centers.

Upon being made aware of a deviation, it must be reported on the PDL in DFexplore. Information that must be reported:

1. Identified by – select your role from the dropdown list.
2. Study Time Point – select the time point in the trial in which the deviation occurred from the drop down list. The time points are generic, to cover multiple trials. Choose the most appropriate one.
3. Deviation Category – select the area in which the deviation occurred.
4. Deviation Description – provide the details of the deviation (e.g., what it was, why it happened, Cycle/Month Number, etc.). Start the description with the form name and month number at which the deviation occurred.
5. Action Taken, addressed by - select how the deviation was dealt with from the drop down list.

There are also 2 check boxes for each deviation that may be used if appropriate.

Med Review Requested

If the deviation pertains to an issue that should be brought to the IBCSG Medical Reviewer's attention, check this box. An automatic email is sent to the Medical Reviewers who may reassess the patient's eligibility upon review of the deviation.

Monitor Note to DMC

If a monitor needs to make the DMC aware of an error on the PDL made by the DM, s/he should check the box and add a query detailing the error. Once the box is checked, an automatic email is sent to the trial-specific email address. The IBCSG DMC reviews the query, makes the change and then resolves the query. Please note the DMs do not respond to this query. They only make the change requested. If there is any confusion regarding the query, the DM emails the monitor.