

iDataFax User Guide

Clinical DataFax Systems Inc.

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iDataFax User Guide

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Abstract

This guide describes the iDataFax tool

Preface

Images in this document are screen shots from **iDataFax** running under Mac OS X. However, functionality is identical under all operating systems, and images are almost identical, except for window decorations.

Instructions to "select" some object can be carried out either by clicking on the object using the mouse, or by keyboarding to it and pressing the **space** or **Return** key.

Instructions to select Menu > Option refer to the selection of options from the menus at the top of the screen. For example, to open the Data window, select View > Data.

The instructions contained in this User Guide are intended to describe, in general terms, how data entry is performed using **iDataFax**. The guidance provided here is not meant to replace more specific instructions which may be provided by the sponsor, principal investigator or coordinating center for a particular trial.

Chapter 1. Introduction

1.1. What is iDataFax ?

iDataFax is a computer program used to enter, review and modify patient data, and to submit it over the internet to a **DataFax** server at the study coordinating center. This type of data entry is commonly referred to as Electronic Data Capture or EDC. **iDataFax** is part of the **DataFax** clinical trial management system, which also supports data collection by fax. Both methods can be used in the same study, but EDC has often been described as having the advantage of providing immediate help to users, resulting in more complete and accurate data entry, and fewer queries from the study coordinating center.

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

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

1.2. What type of computer do I need?

Versions of **iDataFax** exist for: Windows XP and 2000, Mac OS X, Solaris, and Linux. If you plan to use **iDataFax** on more than one computer you will need to install the appropriate version on each computer.

1.3. What type of web browser do I need?

iDataFax is a standalone application. It does not rely on a specific web browser. It may be downloaded and run on your local PC or deployed through an application server hosted by the study sponsor. **iDataFax** communicates with the **DataFax** server using HTTPS on TCP port 443 which is also used by other secure web services such as online banking. This port must be open on any firewalls between the two systems.

1.4. Is data transmission over the internet secure?

iDataFax encrypts all internet transmissions using the same technology used by banks and other secure applications.

1.5. What kind of response time can I expect?

As with all internet applications, this depends primarily on the speed and traffic on your internet connection, and to a lesser extent on the distance between you and the study **DataFax** server. If you have a cable or DSL internet connection, you can expect login times in the range of 5 to 20 seconds and then 1 to 4 seconds to display each new page in the data entry window. Once a page is on the screen, moving between data fields is very fast, with essentially no delay.

1.6. How complicated is this going to be?

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

1.7. Is any patient data stored on my local hard drive?

No - all patient data is sent to and retrieved from the DataFax server at the study coordinating center. As a result, you can access the study from any computer on which **iDataFax** has been installed. And different users can access their studies from the same computer(s). All you need to provide is your login name and password.

1.8. Can anyone impersonate me within iDataFax?

Permission to read, write and modify patient data is defined by the study coordinating center for each **iDataFax** user. These permissions determine which study, sites, patients, assessments and individual data pages each user can create, view and modify. It would not be uncommon for more than one person to have permission to enter data for the same patient at a given clinical site; however, all data entry is recorded with the user's login name, date and time; thus a complete history is maintained of all database transactions. Your login name plus a password constitute your electronic signature. By protecting your electronic signature, and making sure you logout of **iDataFax** before leaving a computer workstation, you can ensure that no one can impersonate you and perform data entry that will be attributed to you.

1.9. How hard is it to navigate among the various study forms for each patient?

Some of the frustration with EDC systems arises from dissimilarity between paper work sheets and data screens, and the difficulty in navigating through the windows of an unfamiliar system to find what you want. By comparison, a patient binder full of printed forms organized by study assessments from beginning to end, with tabs identifying each assessment, is quite easy to use.

iDataFax follows this patient binder analogy. When you open a clinical site (like walking into your office) you will see a list of patient icons (like patient binders on a shelf). Double clicking a patient icon opens the binder to reveal the list of assessments that comprise all patient visits from beginning to end of the study. Double clicking an assessment opens that section of the binder to show the data collection pages for that assessment. When you are finished reviewing or entering data, double clicking an open assessment or patient binder will close it. Each assessment, and page within an assessment, has a text label describing what it is, and colored icons that identify whether it is required or optional, blank or containing data, and, if data is present, whether it is complete or incomplete.

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

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

1.10. Can I use iDataFax for more than one study at a time?

Yes. The login screen asks you to specify the name of the DataFax server at the study coordinating center. Once you connect to the desired server you will see a list of all the studies you are participating in at that center; thus it is possible to use **iDataFax** to participate in many different studies being run by many different coordinating centers. In all cases the software will behave the same; only the study data entry forms will differ.

1.11. If I don't like this, or have time for it, can I switch to faxing?

DataFax is capable of supporting both EDC and faxing data collection forms within the same study, with no additional study setup work. Further, the design of the paper forms and data screens are identical and are completed in the same step; thus switching a clinical site from **iDataFax** to completing and faxing paper forms is certainly possible, and provides a fall-back position for sites that find EDC too time consuming or problematic for whatever reason. Of course, it is also possible to move in the other direction, switching from faxing to EDC.

1.12. How do I get started?

First you will need to download and install **iDataFax** following the instructions provided by the study coordinating center. On starting **iDataFax**, you will see a login screen where you enter the name of the DataFax server at the study coordinating center, your user login name, and your password, all of which will be provided by the study coordinating center.

If your login is successful you will then see a list of the studies in which you are participating at the coordinating center, with a status tag indicating whether each study is currently available or off-line for maintenance. If a study is available, double clicking the study name will open the study database.

1.13. After I connect to a study how do I enter patient data?

If you are not already in the Data view, select it from the View menu in the menubar. The clinical sites in which you have permission to work will then be listed on the left side of the screen. Double clicking a site will open it to reveal the list of patient binders. Double clicking a patient binder will open it to reveal the study assessment tabs, and double clicking a tab will open the assessment to reveal the data entry pages for that assessment. You can then enter data, add reasons to explain unusual values, and reply to outstanding queries from central office.

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

1.14. What do I do when I'm finished entering patient data?

You can close an assessment by double clicking the open assessment tab, and close a patient by double clicking the patient icon. Only one patient binder can be open at a time; opening a new one will automatically close the open one (if any). When you are finished entering data for all patients logout by selecting Exit from the File menu in the menubar.

Chapter 2. A Guided Tour

DataFax includes 3 separate internet tools: DFsystem for user and study administration, DFsetup for creating new study databases, and iDataFax for study data management. This chapter provides a brief introduction to **iDataFax**. It begins with a description of how to login to a DataFax study server, and then describes each of the major components available under the View menu.

2.1. Login

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

- the iDataFax program (Windows and Apple OS X versions are available),
- the name of the DataFax server,
- your login name,
- your initial password, and
- the name of the study (or studies) which you have permission to access on this server.

There are 2 steps to the login process, as illustrated below.

The Login Dialog



In the **iDataFax** the login dialog enter the server name, login name and password, and then select the Login button.

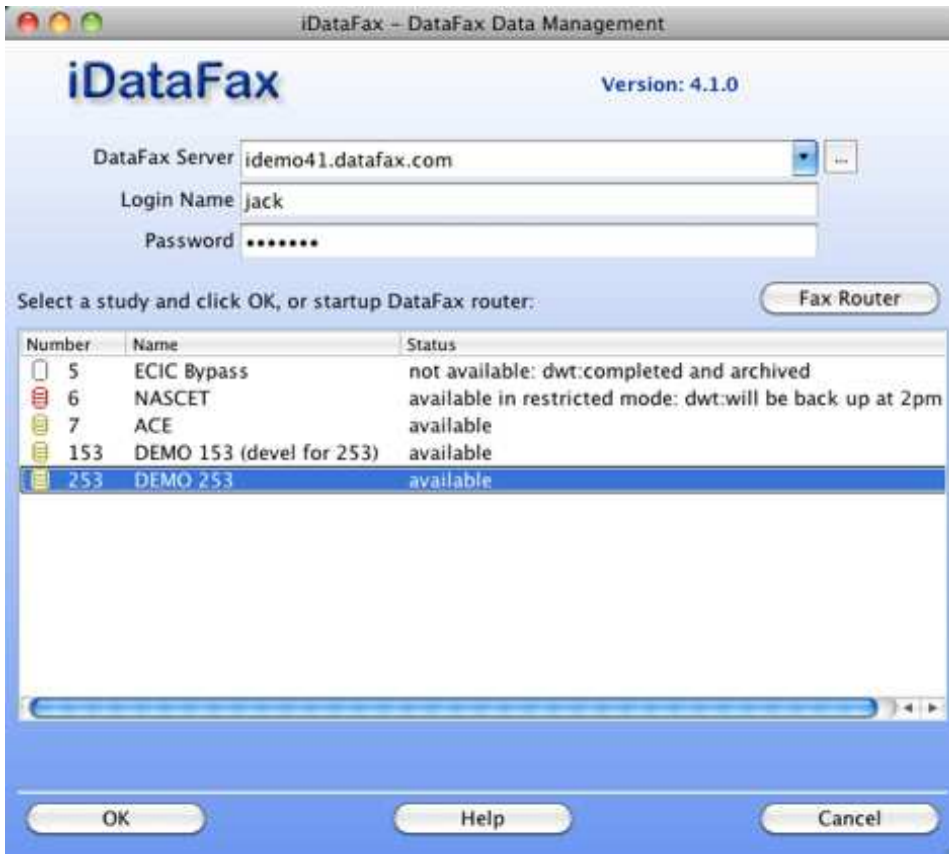
If your IT department has installed a proxy server (to filter requests sent to other servers on the internet) click the button to the right of the 'DataFax Server' name to register the proxy server. You will need to contact your IT department for the necessary information.

iDataFax remembers the most recent servers (and proxy servers) you have used, so you should only need to enter this information once, but your login name and password needs to be entered each time you login.

The first time you connect to a DataFax server you will be prompted to change your password. All data entered and modified is recorded under each users login name. Thus be careful to protect your login name and password.

iDataFax includes password aging, an FDA regulatory requirement. Password expiry may be anytime between 1-9999 days and is set by the DataFax Administrator in the **DFsystem** application. After the expiry period has elapsed you will be prompted to reset your password the next time you login.

The Study Selection Dialog



If login is successful you will see the study selection dialog with a list of studies you have permission to access on the DataFAX server to which you have connected. Each study is identified by number, name and current status (available or offline).

To work on a study, double click the study name, or select it and click the OK button. Press Cancel if you decide not to continue with the login.

Note that both dialogs include a Help button which can be used to access this user guide, which is also available from the Help menu after you login. Thus the user guide is always available, even when you do not have an internet connection.

2.2. User Permissions

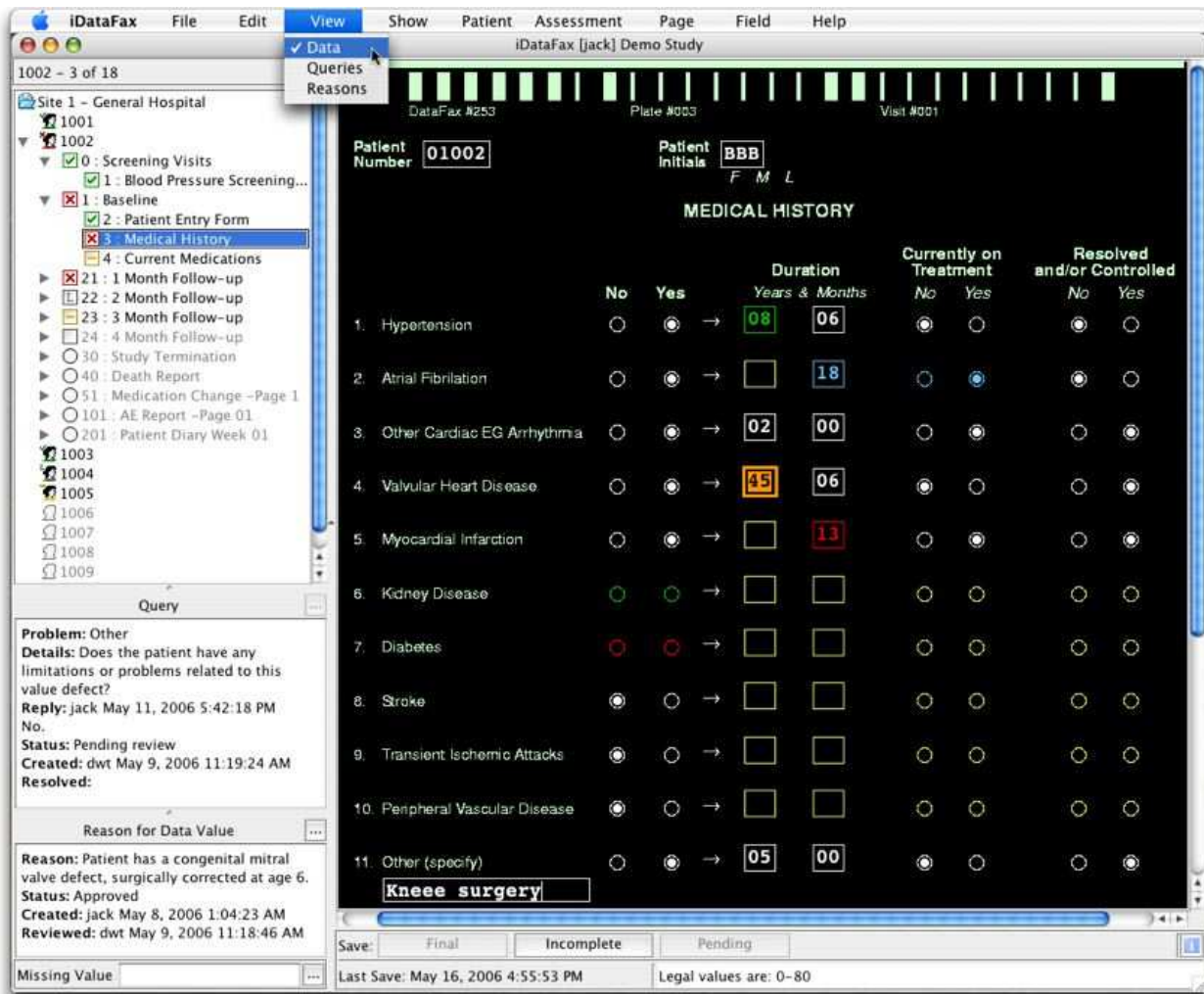
When **iDataFax** opens the study you have selected you will have access to only those patient records and program components that the study managers have granted you permission to use. Typically each participating clinical site will only have access to their own patients, some subset of the available reports, and may have restrictions on which study forms can be seen, modified, printed and exported, and on which views are available. The **iDataFax** views include:

- Data - used to enter, modify and review patient data
- Queries - used to review and respond to questions from the study coordinating center
- Reasons - used to review reasons that were entered to explain particular data values
- Fax - used to enter data from CRF images received by fax
- Reports - used to run and review study reports
- List - used to review and export data records in tabular and SAS formats
- Status - used to review data, query and reason status by work flow levels

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

2.3. Data View

The Data View is the primary **iDataFax** view and is the only view in which patient data, queries and reasons can be entered and modified.



The components of the Data view window (shown above) include the following:


- **Patient Binders.** To enter or review patient data start by selecting a patient binder from the list displayed on the left side of the screen. Each patient binder contains the data forms (CRFs) for an individual patient organized in subsections by study visit or assessment. Each binder is represented by an icon resembling a human head followed by a patient ID number. In the example above the binder is open for patient ID number 1002. You can open only one binder at a time. This locks the patient records giving you exclusive access to the binder until you close it. Patients, assessments and CRF pages are color coded as follows:
 - green - no problems
 - red - some data problems exist
 - orange - data entry was interrupted and remains to be completed
- **The Data Window.** The data window is an exact replica of the study paper CRFs. This is where you enter data values, filling out the form using a keyboard and mouse instead of pen and paper. Data fields are color coded as follows:
 - white - legal values
 - red - illegal values
 - blue - unresolved queries
 - orange - query replies and reasons pending central review

- green - query replies and reasons that have been approved
- **Queries.** Data queries can be attached to any data field, either by someone in the study coordinating center or by a programmed edit check. Blue fields have an outstanding query which will be displayed in the Query window (lower left) when you select the field in the Data window. Queries for missing data and illegal values are automatically resolved and turn green if they are corrected by entering a legal value.

The button in the Query window can be used to open a text window where you can answer the query. This turns the data field orange to indicate that the query has been answered and is pending review by the study coordinating center. If the reply is approved the field will turn green. If the coordinating center has new questions they will revise the query and the field will again turn blue.

- **Reasons.** You may be able to avoid queries by entering a reason to explain an unusual data value. To add a reason to a data field, select the field in the data window and then click the button in the Reason window (lower left) to open a text window where your reason can be typed. Fields with new reasons will turn orange to indicate they are pending review by the study coordinating center. If the reason is approved the field will turn green. If the coordinating center has questions they will add a new query to the field and it will turn blue.
- **Missing Values.** Some studies use standard missing value codes, e.g. NA - not available, ND - not done, etc. which can be applied to data fields when a data value can not be entered. If standard missing value codes have been defined a code can be selected for the current data field by clicking the button in the Missing Value window (bottom left corner of the screen). Fields with missing value codes turn green and the code label is displayed in the Missing Value window when you move into the field. You will not be able to add missing value codes to any field that has been defined as essential by the study coordinating center.
- **Saving Your Work.** After making changes to data fields, queries or reasons, you must select one of the Save buttons at the bottom of the screen to transmit your changes over the internet to the study server. If you are interrupted during new data entry and do not want to lose your work you can save a partially completed page using the Pending button. If you have completed the page and there are no illegal values (red) or outstanding queries (blue) you can save your work using the Final button, otherwise you will need to use the Incomplete button. The data is not stored on your personal computer and will be lost if you do not transmit it using one of the Save buttons. You will be warned if there are unsaved changes and you try to move off the current page.
- **Last Save.** The record creation and modification timestamps written at the end of each data record are entered by the DataFax server in server time. Thus regardless of where the data is coming from, the timestamps in the study database will all be synchronized with the location of the server. As an aid to end users the 'Last Save' date and time, shown at the bottom of the screen in Data View, is displayed in the user's local time, which is determined from the difference at login between server time and the system clock on the computer where iDataFax is running. This may not actually be the user's local time if the user's system clock is not up to date, or if the user is running iDataFax from an application server located in another time zone.

This is the only place where an attempt is made to use local time. List View, audit trail reports, SAS exports, etc. all use server time.

- **The Message Window.** The message window located below the Save buttons displays the date and time of the last Save for the current page, and may also display field level help (e.g. legal values for the current field) that has been specified by the study coordinating center.
- **Images.** iDataFax can store images as well as data. This might include a faxed copy of the paper CRF or a scanned copy of some medical record or test result. If images have been attached to the current page the image icon  will appear in the bottom right corner of the screen. Depending on your user preference settings (see below) you may need to click the image icon to toggle between data and image views, or the screen may split automatically when you go to a page with images. If multiple images exist the image icon will be prefixed with another icon containing the number of

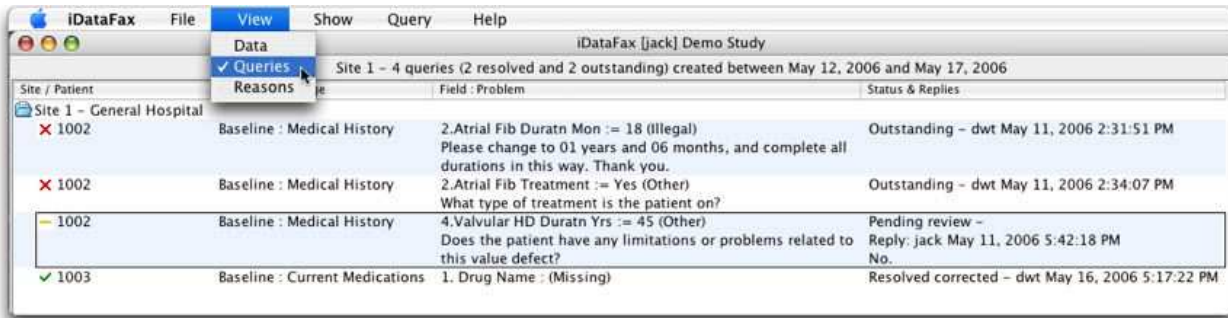
images. Clicking this icon will launch a separate window where you can review all of the images.

- **Menus.** A number of menus are located at the top of the **iDataFAX** window. The example screen, at the beginning of this tour, illustrates the View menu which is used to switch between the different views that you have permission to use in the current study. These menus differ by view and are described in the chapter devoted to each view.
- **User Preferences.** You can customize some aspects of **iDataFAX** behavior using the Preferences dialog located under the File menu. Once set preferences are preserved across login sessions.
- **Auto Logout.** To meet regulatory and patient confidentiality requirements **iDataFAX** was designed with an auto-logout feature which closes the screen after a specified period of inactivity. If this occurs when you have unsaved changes in the current data screen the unsaved changes will be lost, and you will be warned that this occurred the next time you login to the study and asked if you would like to return to the page you were on when this happened. You can thus easily return to the page but any unsaved changes can not be recovered.

Any keyboard input or mouse movement inside the **iDataFAX** window will reset the timer. A default and maximum time will have been configured by the study coordinating center. You can set the timeout interval to a value not exceeding this maximum in the user preferences dialog.

2.4. Queries View

The Queries View lists data queries from the study coordinating center.



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

2.5. Reasons View

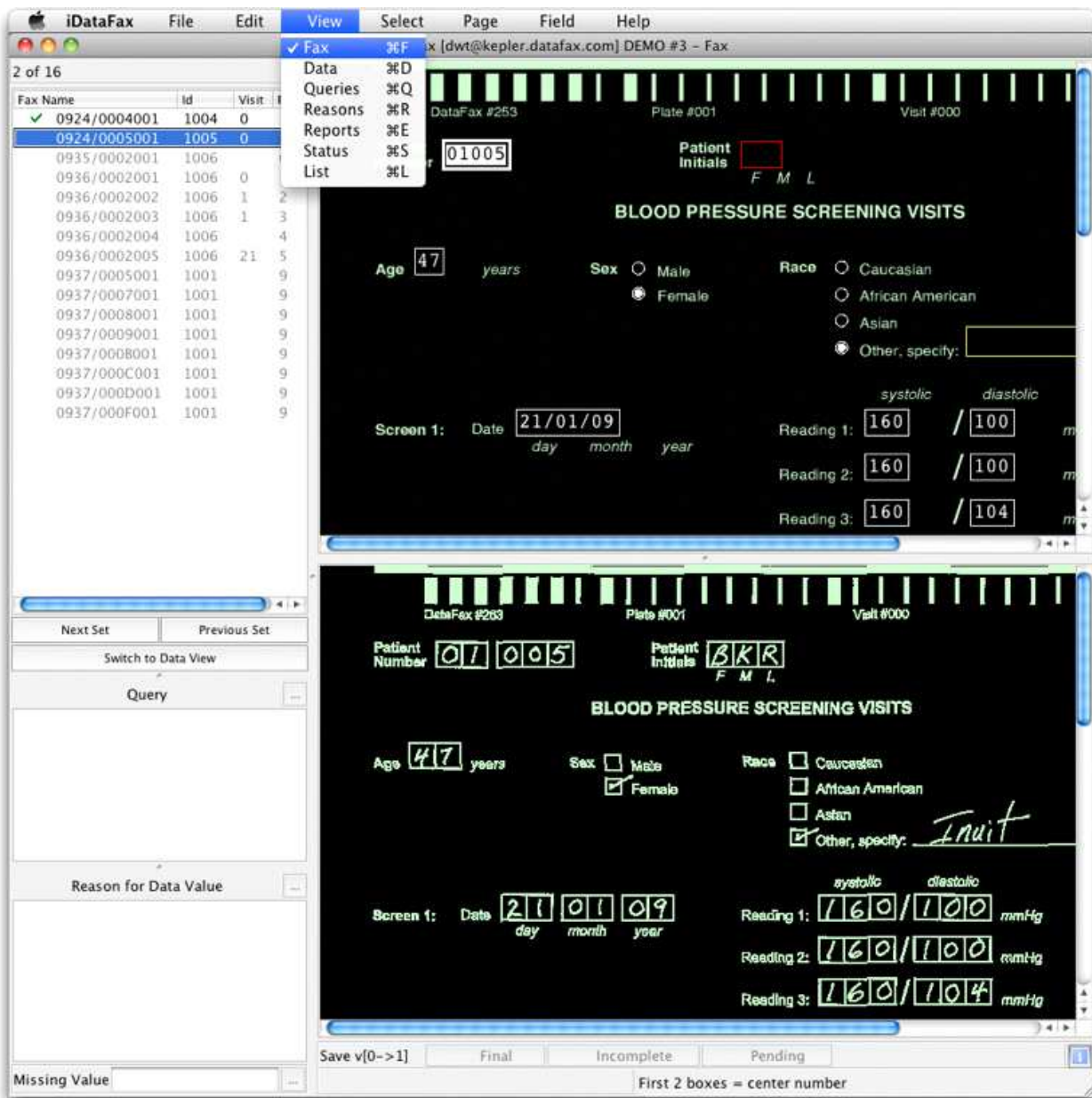
The Reasons View lists any reasons that have been entered to explain particular data fields.

Site / Patient	Field: Reason	Status
Site 1 - General Hospital - 1001	Screening Visits : Blood Pressure Screening	Pending review - jack May 11, 2006 12:51:54 AM
✓ 1002	Baseline : Medical History	Approved - dwt May 11, 2006 2:27:31 PM
✓ 1002	Baseline : Medical History	Approved - dwt May 9, 2006 11:18:46 AM
✗ 1002	1 Month Follow-up : Monthly Follow-up	Rejected - dwt May 16, 2006 5:29:30 PM
- 1002	1 Month Follow-up : Monthly Follow-up	Pending review - jack May 13, 2006 10:53:57 AM

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

2.6. Fax View

The Fax View is used to enter new data records from paper case report forms (CRFs) that have been faxed or emailed to the DataFax study server.



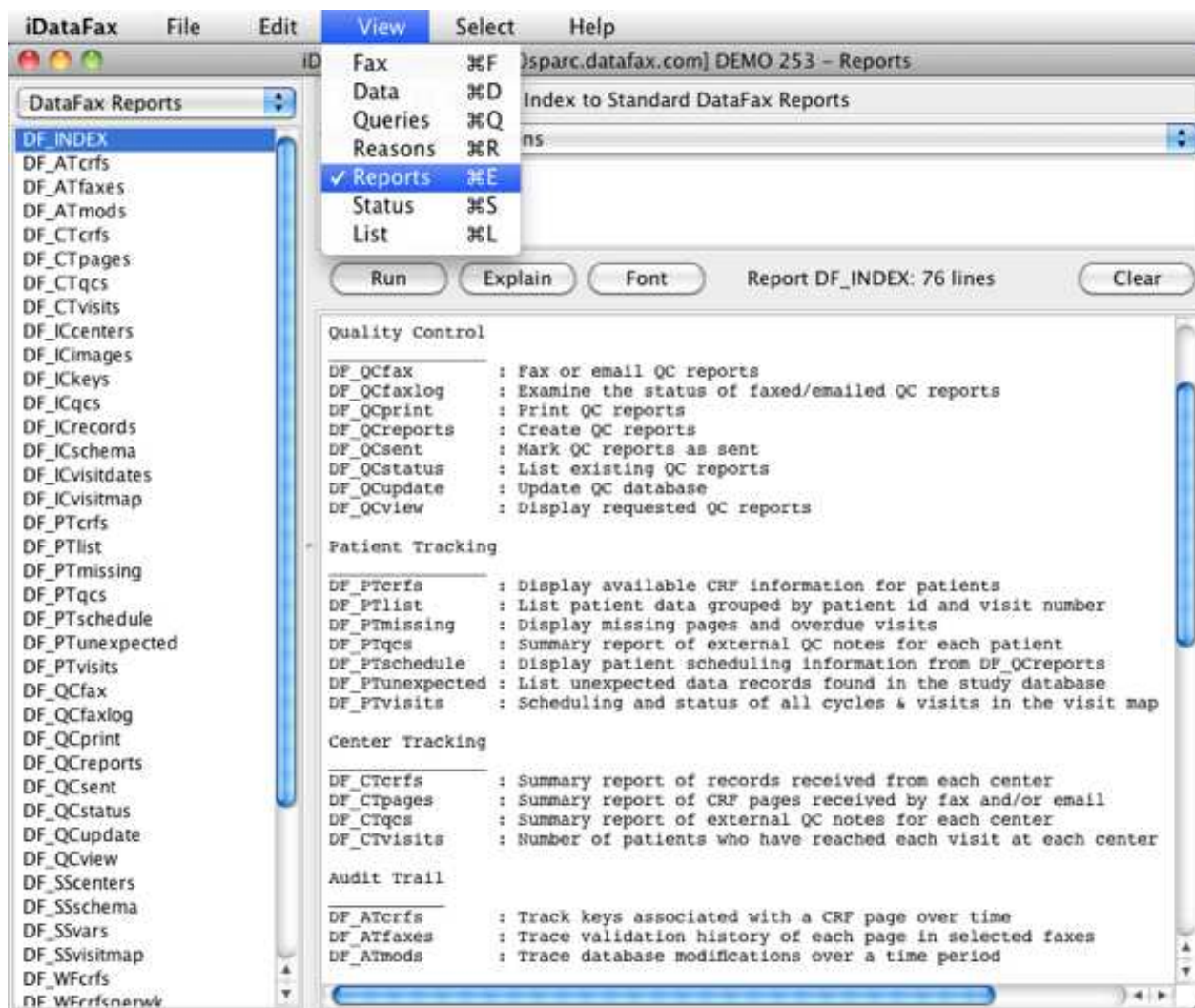
Fax view is identical to the Data view except that the list of patient binders is replaced by a list of faxed pages that need to be entered. Fax View features include:

- **Record Selection Options.** Typically users will chose to enter a fax at a time and request the oldest ones first, but it is possible to request only certain CRF forms and to work backwards from newest to oldest arrivals. These options are specified using the New Record Retrieval Dialog available under the Select menu.
- **Intelligent Character Recognition.** When a CRF page arrives by fax it is immediately scanned and read by the ICR software. Thus most data fields, including: numbers, dates, visual analog scales and check boxes, will already be completed in the data screen. The task of the person using Fax View is thus to correct any ICR errors or omissions, and to add any missing value codes, reasons or queries that may be required.

- **Get Next Set of New Records.** When the user is finished with the current set of records, clicking this button (located below the record list) will release the current set of records and fetch the next set using the selection method previously specified in the New Record Selection Dialog. But until then the user can return to any record in the current set to make corrections, which sometimes become apparent as one works through the pages in a fax.
- **Switch to Data View.** Clicking this button opens the current patient binder in Data View while keeping the focus on the current page to show where it belongs in the binder. The user can then check other data records as needed before switching back to Fax View to complete data entry for the new page.

2.7. Reports View

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



- **DataFax Reports.** DataFax includes a number of standard reports that can be used in any study. The list of reports (which you have permission to run) will appear when you select DataFax Reports (top left).

- **Study Reports.** Any study specific reports created by the study coordinating center will be listed when you select Study Reports.
- **History.** Reports that you have already run during the current login session are saved and will be listed when you select History. Selecting a report in the history list will display the previous output for that report.
- **Options.** Most reports have a number of options which can be selected from the drop down options list to control what the report will produce.
- **Explain.** All of the DataFax Reports, and most Study Reports, come with a description of what they do and how to use the options. This documentation can be reviewed by selecting a report fro the report list and then clicking the Explain button.
- **Run.** To run a report, select it from the report list and then click the Run button. The output will be displayed and added to the history list.

2.8. List View

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

ID	PINIT	EDATE	ELIG	ELIGEX	BDATE	WTKG	WTLB	HTCM	HTIN	PULSE	SMOKE	EXERCISE
1006	BDS	02/01/11	2		07/10/54	076.0	167.5	183	072.0	046	1	3
004												
2005	NNN	22/12/10	2		05/06/32	070.5	155.5	170	066.9	092	3	2
2006	PWR	10/09/10	2		06/07/40	065.5	144.4	180	070.9	070	4	4
5	02007	TIF	11/11/10	2	12/06/40	083.2	183.5	208	082.0	068	2	1
6	02008	POP	08/06/10	2	04/05/31	060.5	133.3	175	068.8	067	1	1
7	02009	QWE	11/09/10	2	12/07/50	070.5	155.5	166	065.4	059	2	3
8	02011	JOK	19/08/10	2	13/05/33	080.3	177.0	197	077.7	069	2	2
9	11002	BBB	15/01/11	2	14/03/85	070.0	154.3	185	072.8	070	1	1
10	13002	ABC	02/01/10	2	01/01/60	150.0	330.7	150		031	1	1
11	15001	JRF	02/01/11	2	19/03/74	064.4	140.0	168	066.0	056	1	3
12	15002	JMP	05/12/10	2	04/10/70	067.0	147.8	175	068.9	052	3	2
13	15003	RTW	01/03/11	2	02/01/64	070.5	155.5	174	068.5	055	2	1
14	15004	TYR	02/02/11	2	03/03/55	072.6	160.0	160	063.0	051	4	1

Switch to Data View

Query

Problem: Inconsistent (reply required)
 Details: Initials (TIF) on this page differ from initials (TIR) from Visit 0 Plate 1
 Status: Outstanding
 Created: dwt June 22, 2011 16:44:10
 Resolved:

Reason for Data Value

Missing Value

Save [1] Final Incomplete Pending view mode 2

Last Save: June 22, 2011 16:36:33 Use underscore for missing initials, e.g. M_T

- **Permissions.** A plate is selected from the list of study plates in the left panel. Only plates which you have permission to see will be shown, and when a plate is selected, only those records which you have permission to see will be shown as rows in the table, and columns will be hidden for any data fields you are not allowed to see.
- **Selecting Data Fields.** Data fields (columns) can be selected and reordered using the Field Selection dialog available under the Select menu.
- **Selecting Data Records.** You can search for data records with specific attributes (e.g. illegal values, outstanding queries, pending reasons, etc.) using the Search dialog available under the Select menu.
- **Selecting Predefined Views.** Some users may have permission to define views, consisting of selected data records and data fields, for others to use. Views are created using menu item 'Select-Define Views' and accessed using 'Select-By View'.
- **Making Changes to Data, Queries and Reasons.** You can not modify data values, queries or reasons directly in List view, but double clicking on a data field takes you to that field in Data View where changes can be made (if your permissions allow it). To return to List View from Data View select the Return to List View button.
- **User Preferences.** The Preferences dialog, located under File menu, includes options for customizing List View including: field color coding, displaying codes vs labels, date formats and column titles.

2.9. Status View

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

The screenshot shows the iDataFAX Status View interface. At the top, there are filter fields for 'Pages awaiting review in the Unidentified Fax Router' (value 3) and 'Pages awaiting review in the Study New Fax Queue' (value 4). Below these are input fields for 'Site', 'Patient ID', 'Assessment', and 'Page', with 'Update' and 'Clear' buttons.

The main content area is divided into three sections: 'Data Records', 'Queries', and 'Reasons'. Each section contains a table with columns for 'Level', 'Pending', 'Lost', 'Incomp', 'Final', and 'Total'.

Below the tables are three bar charts, each corresponding to one of the sections. The first chart shows 'Data Records' with categories Pending (orange), Lost (grey), Incomplete (red), and Final (green). The second chart shows 'Queries' with categories Pending (orange), Unresolved (blue), and Resolved (green). The third chart shows 'Reasons' with categories Pending (orange), Rejected (blue), and Approved (green).

At the bottom, there is a 'Study Users' table with columns for 'Login', 'Host', 'Tool', and 'Since'. The last update time is shown as '3/5/08 11:13 AM'.

Level	Pending	Lost	Incomp	Final	Total
0	5				5
1			28	19	47
2			6	5	11
3			1	2	3
4		1	2	3	6
5					
6					
7					
Total	5	1	37	29	72

Level	Pending	Unres	Reslvd	Total
0		53		53
1	1	51	13	65
2	1	33	14	48
3			2	2
4		23		23
5		2		2
6				
7				
Total	2	162	29	193

Level	Pending	Rejctd	Apprvd	Total
0	2		2	4
1	3	1	15	19
2	2		11	13
3			10	10
4			6	6
5				
6				
7				
Total	7	1	44	52

Login	Host	Tool	Since
1 jack	localhost	iDataFAX	2008/03/05 11:09
2 dwt	localhost	iDataFAX	2008/03/05 11:13
3 dwt	localhost	Setup Tool	2008/03/05 11:10
4 angela	localhost	iDataFAX	2008/03/05 11:12

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

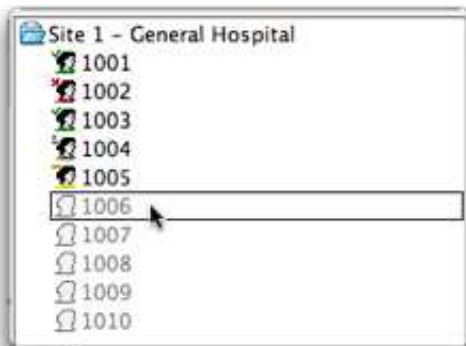
Chapter 3. Using iDataFAX

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

3.1. How do I select the correct patient binder for a new patient?

In many studies patients are numbered sequentially as they enter the trial, but in some studies patient ID numbers are random and assigned on study enrollment or randomization. In either case, patient IDs must be registered in the DataFAX study setup at the coordinating center before they will be available in **iDataFAX**.

The Patient Binder List



To see the patient binders available for your site, select View > Data. If you work at more than one study site you will need to double click on a site to open it. You will then see a list of patient binders, identified by head icons and patient ID numbers in ascending numeric order, on the left side of the screen. Binders that are in use are represented by an active icon. Unused binders appear muted with an empty head icon. In most cases, the first unused binder in this list will be the correct binder for the next patient. Double clicking the binder will open it.

Patient - Start New Patient



If the patient ID number you need is not in the patient binder list, select Patient > Start New Patient, and enter the patient ID number as shown in this example. When you select OK, a new patient binder will be added to the list with the specified patient ID, and the binder will open automatically.



Note

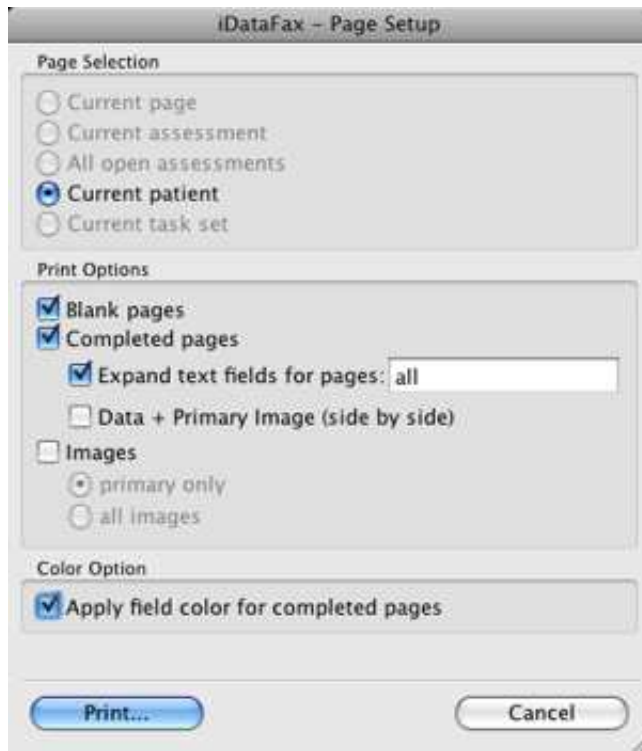
If instead of a new patient ID, you enter one that already exists in the patient binder list, that binder will open when you click OK. If the binder is already in use, the head icon and one or more of the assessment icons will be active, not muted and empty.

3.2. Can I print a copy of a patient binder?

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

You have 2 options, with very similar dialogs, File > Print (shown below) and File > Save As PDF.

File - Print



To print patient CRFs:

1. Select View > Data to open the data view
2. Double click the patient binder to open it
3. If you only want to print selected pages open the corresponding assessments
4. Select File > Print to open this dialog
5. Select one of the Page Selection options
6. Select one or more of the Print Options:
 - Blank Pages - CRF pages which do not yet contain data
 - Completed Pages - CRF pages containing data values
 - Expand text fields - to avoid truncating long text entries
 - Data + Primary Image - to see both the data and the supporting CRF
 - Images - any faxed or scanned images that exist for the selected pages (primary only or all images)
7. Check Apply field color if you want the data fields printed in the current color shown in iDataFAX.
8. Click Print

In the example above, the Current Assessment is selected and both Completed and Blank Pages are checked. This produces one copy of each page in the current assessment, with data values included on pages where data has been entered.



Note

The patient ID number and assessment number are printed on every page, even if you select Blank Pages. Make sure you have selected the correct patient binder before printing it.

3.3. How can I make sure that I'm completing the data forms correctly?

Here are the steps we recommend:

1. Double click a patient binder to open it
2. Double click all of the assessments you want to open
3. Click the page you want to start on. It will then appear in the data window. You can go to any page at any time by clicking it in the patient binder list. Also, the up and down arrow keys can be used to move through the pages of the all the assessments you opened
4. When you have found a page you want to work on, press the **Tab** key or click anywhere in the background of the data window. This will put the focus on the first data field at the top of the page, and the field will be highlighted
5. Complete the first data field using the keyboard to enter text and numbers, or the mouse to select a choice option or move a visual analog slider. Choice options can also be selected using the number keys: 1=1st option, 2=2nd option, etc., and visual analog fields can also be completed by using the right and left arrow keys to move the slider along the scale
6. If a help message has been specified in the study setup it will appear at the bottom of the data window
7. As you enter values watch the field color. It will change from red (required fields) or yellow (optional fields) to white when a legal value has been entered. The help message is often used to display the legal values expected for each field
8. After you complete the first field use the **Return** or **Tab** key to move to the next field. Continue in this way to complete all fields on the page. This will ensure that you walk through all fields in the order planned by the form's designer. Some fields may have edit checks that are triggered as you move in or out of them. Moving through all fields will ensure that all of the edit checks are triggered, and thus that you will be notified of any problems
9. Some edit checks may also be triggered when you select Final, Incomplete or Pending to save your changes. But those edit checks which have been setup to trip on field entry or exit will only fire if you move through the data fields
10. Read any warning or error messages displayed by edit checks carefully, and take any necessary action to correct or explain any unexpected values
11. You can move backward through the fields using **Shift+Tab** and **Shift+Return**
12. When you have completed all of the fields on the page remember to save your work by clicking one of the 3 Save buttons at the bottom of the screen:
 - Final - if all fields have been completed and there are no red or blue problem fields
 - Incomplete - if any field is still incomplete, or there are unresolved queries or illegal values
 - Pending - if any field is incomplete and you want to complete the page before it is reviewed by the study coordinating center



Note

Pending can not be used after a page has reached Final or Incomplete status, and Final can not be used if the page still has problem fields.

13. If you can not locate the problem fields select Page > List All Outstanding Problems on This Page, and a dialog will appear listing the problems that are preventing you from saving the page with status Final.
14. After you save a page, the next page that is open in the patient binder list (if any) will be opened in the data window, with the focus on the first field at the top of the page
15. Continue in this way to complete all pages in the assessment(s) you have opened. Note that those assessments and pages with a square icon are required, while those with a circle icon are optional (i.e. not required for all patients). However, an optional page may become required if some specified condition is met, thus you may find a missing page query on what appears to be an optional page
16. Examine the icons for each page you have completed to confirm that you have saved them with the correct status. Those with a green check mark have been assigned Final status, those with a red X are Incomplete, those with a yellow dash have been marked Pending, and any page with an empty

icon has not yet been completed

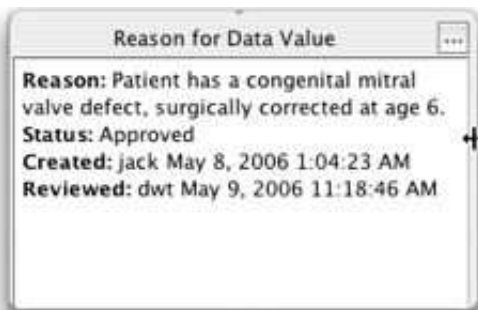
17. When you are finished with a patient binder double clicking the head icon will close it. The current binder will also close if you decide to open a different one. Remember that only one patient binder can be open at a time, and while you have it open, no one else will be able to use it (except in view only mode)
18. When you are finished entering study data, or if you need to pause for more than a few minutes, exit from the **iDataFax** application. Do not leave your PC unattended while you are logged in to the study database

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

Yes. This is a good way to avoid queries from the study coordinating center. Adding a new reason, or modifying an existing reason, for any problem field (red or blue), creates a pending reason (orange) which solves the problem, pending review by the study coordinating center. Dealing with all problem fields this way will allow you to indicate that you are finished with the page by selecting the Final button when you save your modifications.

How can you tell if a data field has an associated reason? When the focus rests on a data field, all meta-data (queries, reasons and missing values) for that field are shown in the metadata windows below the patient binder list. If the field already has a reason, it will be displayed in the Reason for Data Value metadata window (illustrated below), otherwise this window will be empty.

The Reason Metadata Window



The reason metadata window shows:

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

To add a new reason or modify an existing one, either click the button in the upper right corner of the reason metadata window shown above, or select Field > Add Reason for Data Value.

Field - Add Reason for Data Value

The add reason dialog shows:

- Field - a label describing the current field
- Old Value - the value the field had when the page was opened
- Reason - the current reason (if any) for the old value and who created it and when.
- New Value - the current value in the data field
- Status - new reasons are created with status pending, unless the user has permission to approve reasons
- Reason - a text widget where a new reason can be entered

Some fields may require a reason when you change them. In such cases this dialog will appear automatically when you leave the field. You can then either enter a reason or use the Revert to Old button to undo the change. Once a reason has been entered the OK button is used to apply it. The new reason will then appear in the Reason metadata window.

When a reason is created by a user who has permission to approve reasons, the status is automatically set to approved, but the Status button is active and can be used to change the status of the new reason.

**Note**

Remember that no changes are saved until you select one of the Save buttons at the bottom of the data screen. This applies to both data and metadata (queries, reasons and missing values).

3.5. Can I use standard missing value codes?

Yes. DataFax supports missing value codes which may be predefined for each study to provide standard accepted reasons for missing data. If missing value codes have been predefined for your study, you can assign one of them to the current data field by selecting it from the list displayed when you click the button on the Missing Value metadata window (shown below and located in the bottom left corner of the screen), or using Field > Mark Field Missing.

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

After applying a missing value code to a data field in either of these ways keyboard shortcut Control+M (Command+M on Mac OS X) can be used to apply the same missing value code to other data fields.

If you need to remove a missing value code so you can enter a real data value, select the No Code (reset) option which appears at the bottom of the list of missing values.

Missing Value Metadata Window



Note

If a data field has been defined as 'essential' you will not be able to select a missing value code.

3.6. What are queries and where do they come from?

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

There are 4 types of queries:

1. Data Correction Queries - request a correction to a data value or a blank field
2. Data Clarification Queries - ask you to reply to a question
3. Overdue Visit Queries - identify study assessments which should have been performed by now
4. Missing Page Queries - identify required pages that have not been completed

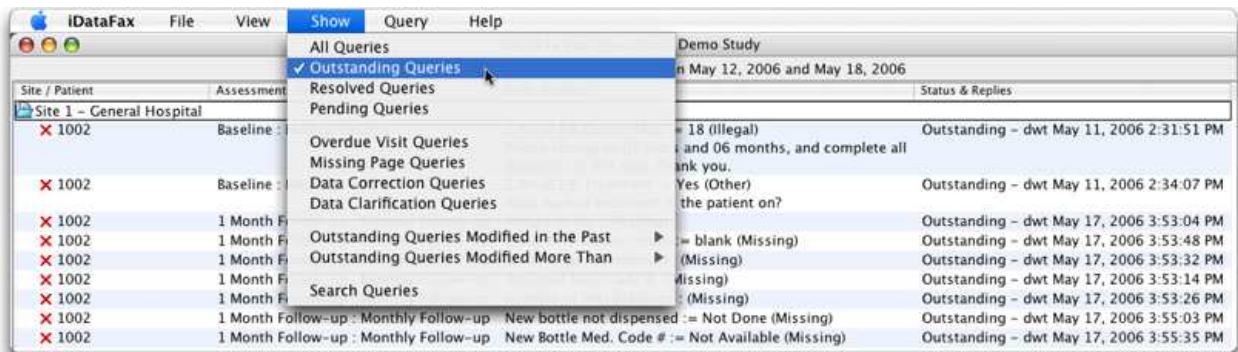
Data Correction and Data Clarification queries are classified into one of the following general problem types:

- Missing - the field is blank and needs to be completed
- Illegal - the field failed the legal range test
- Inconsistent - the field contains a value that is inconsistent with the value in some other field
- Illegible - a paper CRF page has handwriting which is unclear
- Fax noise - a faxed page had transmission errors
- Other - some other problem described in the query details

In some cases, such as when the problem type is Missing or Illegal, no further information may be needed to communicate the problem. But when necessary, the query will include details describing the problem and might also suggest the expected corrective action.

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

3.7. How do I find all outstanding queries?



- Select View > Queries to open the queries view
- Select Show > Outstanding Queries. All outstanding queries (marked with a red X) will be displayed. If none are displayed you have no outstanding queries - congratulations!
- Double click an outstanding query from the list to jump to the data field with that query in the data view, where you can review and respond to it

If you resolve a query, it will be removed from the list when you return to the Queries view.

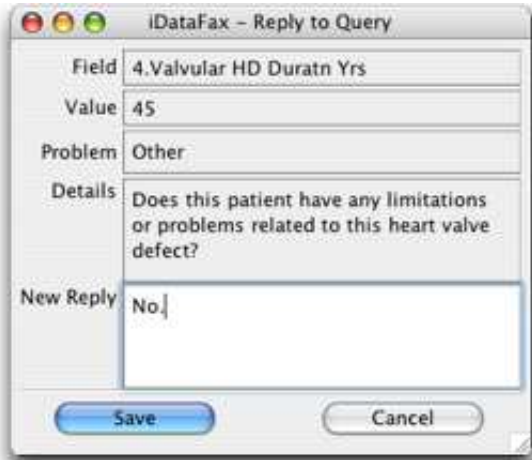
3.8. How should I respond to queries?

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

Other queries ask a question to which a reply is expected. These queries are identified by the phrase (reply required) at the top of the Query metadata window. When a reply is entered the field turns orange and query status changes to Pending, to indicate that the reply is ready for central office review.

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

Field - Reply to Query

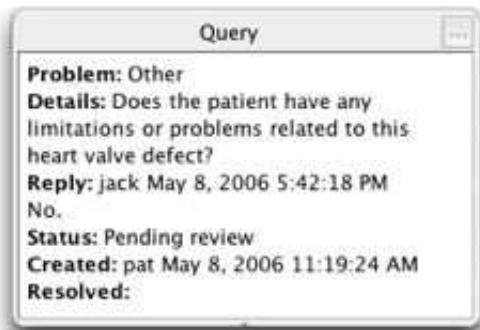


To reply to a query, click the button in the upper right corner of the Query metadata window, or select Field > Reply to Query.

The Query reply dialog shows:

- Field - the current field and it's value
- Problem - the problem type: Missing, Illegal, Inconsistent, Illegible, Fax noise, or Other
- Details - a description of the problem (if necessary)
- Old Reply - previous reply to this query (if any)
- New Reply - a space where the new reply can be entered

The Query Metadata Window



When the focus moves to a data field which has a query, the query is displayed in the Query metadata window. If the field does not have a query this window will be empty.

The Query metadata window contains:

- Problem - the problem type
- Details - a description of the problem (if any)
- Reply - the reply to the query (if any)
- Status - the current status of the query
- Created - who created the query and when
- Resolved - who resolved the query and when

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

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



Note

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

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

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

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

When you respond in one of these ways, the data field will change from blue to green if the response resolves the problem, or orange if the response needs to be reviewed by the study coordinating center.

3.11. Can I indicate that a patient assessment is unavailable?

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

Assessment - Mark Assessment Lost



To mark an assessment lost:

1. Select View > Data to open the data view
2. Double click the patient binder to open it and display the study assessments
3. Click on the assessment in the patient binder list
4. Select Assessment > Mark Assessment Lost. This opens the dialog, shown here. After you select the reason category (Why) and explain why the assessment is lost (Details) the Save button will become active

When you click Save all of the pages in the assessment will be marked lost and the lost symbol 'L' will appear in the assessment and page list on the left side of the screen.

Whenever a lost record is selected the reason specified when the assessment was marked lost will appear in the 'Reason' window in the bottom left corner of the **iDataFax** window.

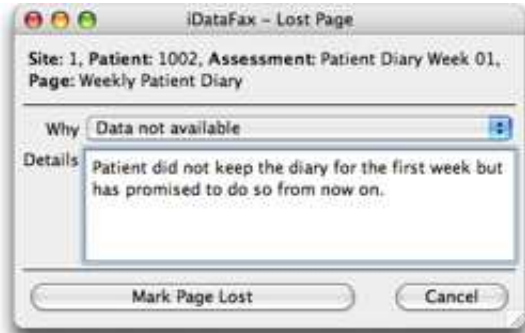
If an overdue visit query exists it will be removed when the assessment is marked lost.

Once an assessment has been marked 'Lost' data entry will be blocked for all pages in the assessment. If you discover that it was a mistake to mark an assessment lost select the assessment in the record list and then select Unmark Lost from the Assessment menu. This will remove the 'Lost' flag and enable data entry for all pages in the assesment. It is also possible to remove the 'Lost' flag from individual pages by selecting the page and then selecting Unmark Lost from the Page menu.

3.12. Can I indicate that a page is unavailable?

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

Page - Mark Page Lost

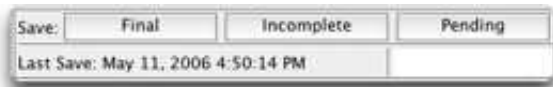


To mark a page lost:

1. Select View > Data to open the data view
2. Double click the patient binder to open it and display the study assessments.
3. Double click the assessment to open it
4. Click the page you want to mark lost. It will appear in the data window
5. Select Page > Mark Page Lost. This opens the dialog, shown here, where you can select the reason category and enter details describing the circumstances
6. When you click Mark Page Lost, the lost symbol 'L' will appear in the page icon

3.13. Do I need to save the changes I have made?

Save Buttons



Yes. None of the changes you make to data fields or metadata (queries, reasons and missing values) will be saved until you select one of the save buttons at the bottom of the data window. If you try to close the current page or open a different page without saving changes, a dialog will appear asking if you want to save or discard your changes before opening the new page.

The Save options include:

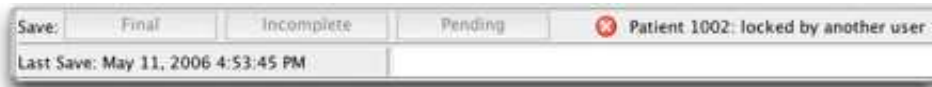
- Final - use this option if all fields have been completed or explained with reasons, all queries have been answered, and you know of no other changes that are needed to complete data entry. A green check mark will appear in the page icon
- Incomplete - use this option if any field is still incomplete or any query is still outstanding. A red X will appear in the page icon
- Pending - use this option if you are not finished with the page and want to work on it some more before it is reviewed by the study coordinating center. A yellow dash will appear in the page icon

There are two restrictions:

1. Pending will not be available once a page has reached Final or Incomplete status if your permissions only allow Pending to be used during new data entry. If this is the case the Pending button will be inactive to prevent a mistake
2. Final can not be used if there are any red or blue fields on the page, i.e. any problem fields which have not been corrected or addressed using one of the 3 metadata options (i.e. replying to a query,

adding a new reason, or assigning a missing value code). In this situation the Final button will be inactive

When a Patient is Locked



iDataFax uses patient level locking, which ensures that only one user can work in a patient binder at a time. The binder is locked when you open it and released when you close it. It will also be released if your **iDataFax** session times out. If you try to open a patient binder which is locked by another user, a dialog will appear asking if you want to open it in view only mode. While in view only mode, the Save buttons will be inactive and a message indicating that the patient is locked by another user will be displayed at the bottom of the Data window.

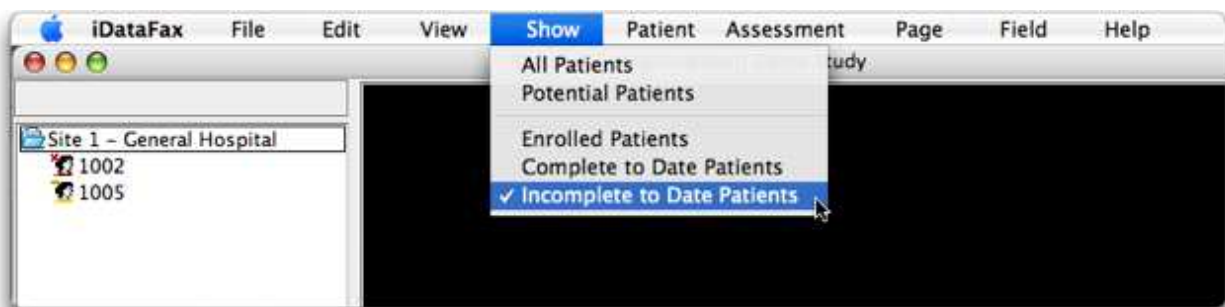
Even if you are the only person with permission to enter data into patient binders at your site, remember that someone at the study coordinating center will have permission to review, and approve or reject, new reasons for data values and replies to queries that you have entered. This too will lock a patient binder until the review is completed - typically only a few minutes.

3.14. Can I undo all changes I have just made to a page?

Yes, but only if you have not yet selected one of the save buttons. Select Page > Revert to Last Save to undo all changes to data fields and metadata (queries, reasons and missing values) and return the page to the state it was in when you opened it. This is the only undo level available. Once you have selected one of the Save buttons (Final, Incomplete or Pending), you can not revert to a previous state.

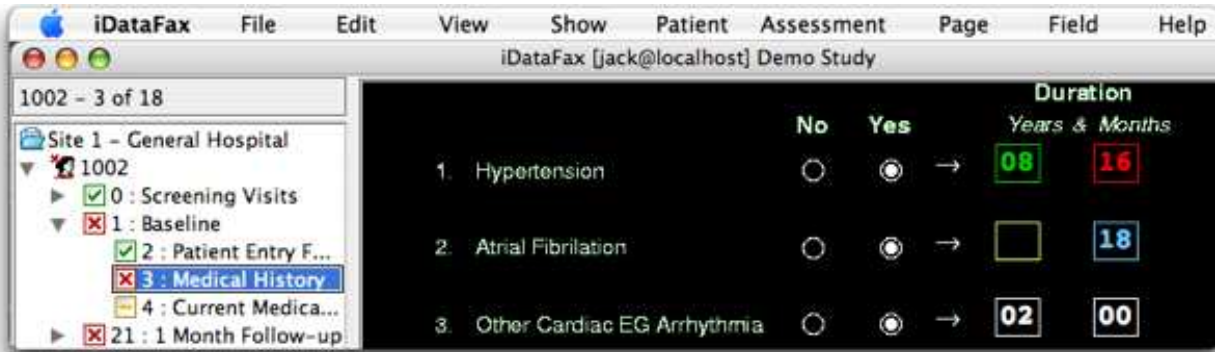
3.15. What's the best way to find all outstanding problems?

Start by reducing the patient binder list to just those patients that have Incomplete and/or Pending pages.

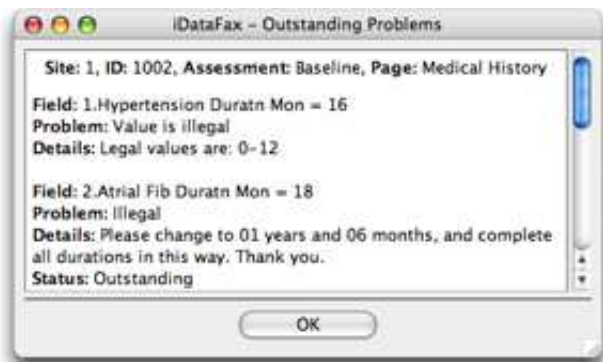


If no patient binders appear in the list, congratulations - you have no outstanding problems. Otherwise, for each patient binder proceed as follows:

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



As shown below, in addition to looking for the red and blue fields, it is possible to get a list of all outstanding problems on the current page.



To list all problems on the current page select Page > List All Outstanding Problems on This Page.

3.16. Why did my iDataFax session Auto Logout?

For regulatory reasons, related to confidentiality of patient data and the requirement that data entry must be attributable to an authorized individual user, you must exit **iDataFax** as soon as you are finished with it, or when you need to leave the computer unattended for any reason.

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

**Note**

If this occurs, any unsaved changes to the last page you were working on will be lost, and the patient lock will be released so that other authorized users can access the patient binder.

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

Auto Logout Dialog

How to prevent an Auto Logout.

While the **iDataFax** application has the focus on your computer screen, the timer is reset by:

- any keyboard action, including just tabbing through fields
- any mouse action, including just moving the mouse

If you switch to a different application, **iDataFax** will lose the focus and the timer will begin to count down.

Of course, logging out yourself after saving your work is the best way to avoid an Auto Logout.

If your last **iDataFax** session timed out, you will see the dialog shown below the next time you login to the same study, and you will be given the opportunity to return to the same Data, Query or Reason view that was on screen when the Auto Logout occurred.

Returning After an Auto Logout

If on Auto Logout there were unsaved changes to a page, the page will be identified by patient ID number, Assessment number, and Page number, and you will be able to return to it by clicking Yes.

**Note**

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

3.17. How should I exit from iDataFax ?

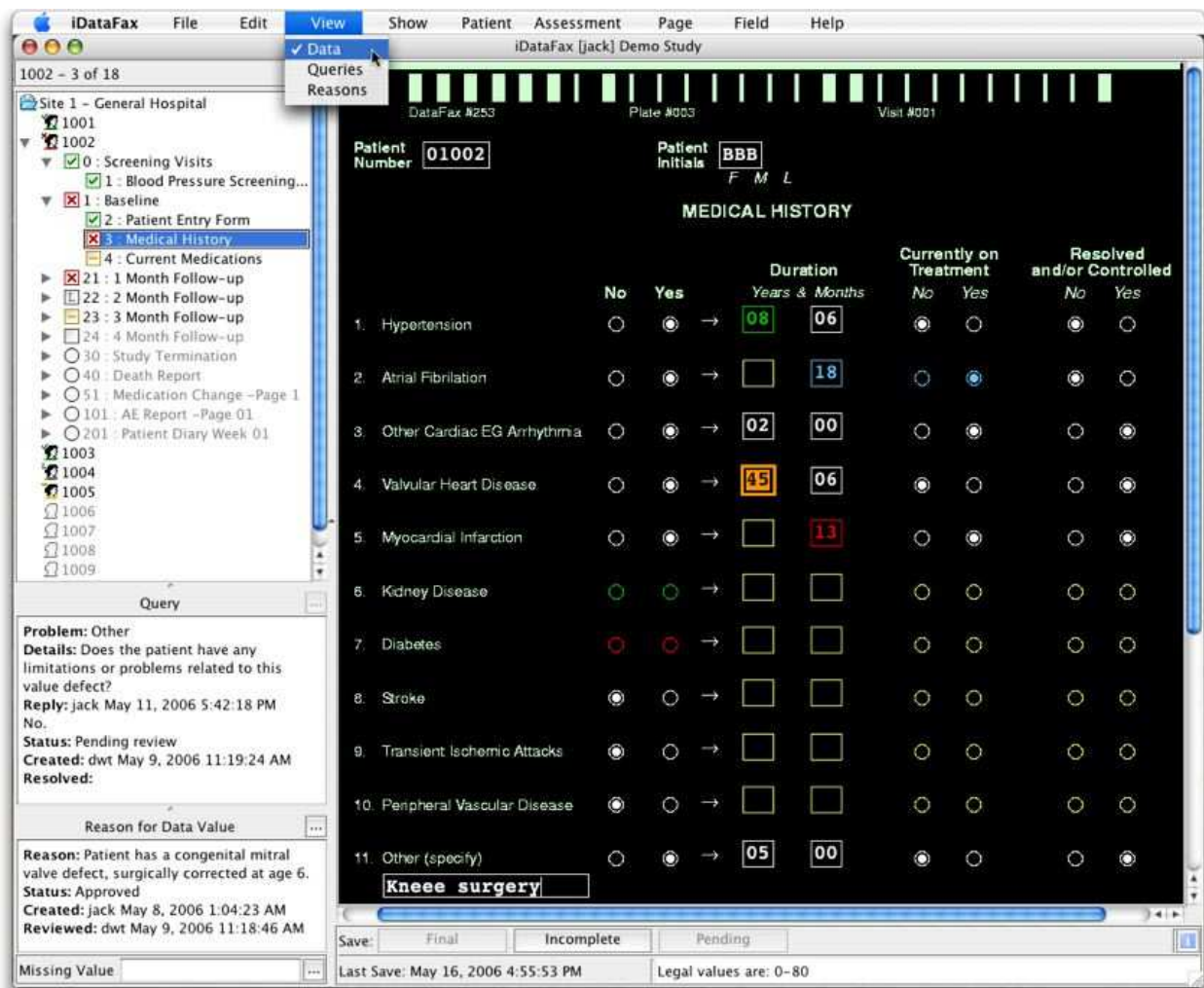
First make sure that you have saved any changes to the page you are currently working on. If you forget you will be warned when you try to exit. When you are finished working in a study, you can close the study or quit the entire **iDataFax** session.

- To close the study but remain connected to the DataFax server so you can select a different study database to work in, select File > Close Study This will take you back to the same study selection window that appears during login
- To disconnect from the DataFax server and end your current **iDataFax** session, select File > Exit

3.18. What should I do if I have questions?

First attempt to find an answer within the online User Guide available under the Help menu in the menubar. If this fails contact the study coordinating center for assistance.

Chapter 4. The Data View








The Data View is the main iDataFax window. It provides access to all patient binders for data entry and review.

4.1. Patient Binders




The Data View is organized like a bookcase full of patient binders. The binders, represented by people icons, are nested under the clinical sites, and displayed in a list on the left side of the window. Only sites and patient binders you are allowed to work in will be visible.

Double clicking a site opens it, revealing the patient binders; and double clicking a binder opens it, revealing the different sections, one for each patient assessment. Assessments can be opened by clicking the arrow or double clicking the assessment label. This reveals the pages belonging to each assessment. Only one patient binder can be open at a time, but you can open as many assessments within the binder as you wish. Double clicking the label for an open assessment, patient or site will close it. Opening a new binder, or a new site, will automatically close the current one.

Different icons and colors indicate the status of patients, assessments and pages. Patient icons include:

-  Empty head - a new binder, not yet started
-  Green head - no problems, all pages entered so far are complete
-  Red head - one or more pages are incomplete
-  Yellow head - one or more pages are pending, and no pages are incomplete
-  'L' head - all pages completed so far have been marked lost (i.e. unavailable)

Assessment and page icons use the same colors, with the same meaning, but they come in different shapes to indicate whether they are required.

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

A square button at the top of the navigation panel can be used to toggle between patient binder and record list navigation. The example shown above illustrates patient binder navigation (note: the toggle button is hidden beneath the View drop-down list). In record list navigation the binders are replaced by columns showing: record status, site#, patient#, visit#, plate# and workflow level# for all records in the current patient binder, without needing to open each visit. It can also be used when working on a task set, in which case only task records are shown.

Visits and the pages within each visit are shown in visitmap order (specified during study setup), regardless of which navigation method is used.

4.2. Metadata: Queries, Reasons and Missing Values

In addition to having a value, each field in the data window can have other information, referred to as metadata. If the current field in the data window has metadata, it is displayed in the bottom left corner of the **iDataFax** window, below the patient binders. The 3 sub-windows correspond to 3 types of metadata, which are:

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

You can reply to a query by clicking the button on the Query window, or selecting Field > Reply to Query and entering up to 500 characters of text. When a reply is entered, the Query status will change to Pending.

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

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

- Reason - reasons can be entered to explain unusual data values by clicking the button on the Reason window. A dialog will appear where you can type a reason (500 characters maximum) or select one of the standard reasons defined for the study. For example, if a field turns red because the value you have entered is considered illegal, you could add a reason to explain the value which might be enough to avoid receiving a query from the study coordinating center.

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

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

- Missing Value - if the study has been configured to use one or more predefined reasons explaining why a field may be missing, you can select one of these reasons using the button on the Missing Value window, and keyboard shortcut Control+M (Command+M on Mac OS X) can be used to apply the most recently used missing value code to a new field. However, a missing value can not be assigned to fields defined by the study coordinator as essential.

4.3. Data Field Colors

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

The colors used for fields without metadata are:

- White - legal values
- Red - illegal values or blank required fields
- Yellow - blank optional fields

The colors used for fields with metadata are:

- Blue - fields with outstanding metadata: an unresolved query or a rejected reason
- Orange - fields with pending metadata: a reason or query reply that has not yet been reviewed by the coordinating center
- Green - fields with approved metadata: a resolved query, an accepted reason, or a predefined missing value code

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

4.4. Entering Data and Metadata

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

The current field will be highlighted in the data window. If legal values or other help text has been defined for the current field it will appear in the bottom right corner of the **iDataFax** window.

All entry of data values and metadata (query replies, reasons and missing values) apply to the current field. So, make sure the correct field is highlighted in the Data window before entering data and metadata.

Choice fields, which allow you to select one of the listed response options, are displayed with a small circle beside each option. The circle is filled in for the current option, if any. You can select a response option by clicking on the circle with the mouse, or by using the number keys - 1 for the first option, 2 for the next, etc. The current option can be removed, returning the field to blank, using the **Delete** key.

String fields are limited to the printable 7-bit ASCII character set, also known as US-ASCII, used in English text. Thus currently **iDataFax** blocks the entry of the accented or unicode characters used in many other languages. **iDataFax** also blocks the '|' character which is reserved for use as the field delimiter in data and metadata records.

4.5. Saving Data and Metadata

Changes made to each page need to be saved before you move to the next page. If you click on a different page before saving changes, a dialog will appear asking whether you want to save or discard the changes you have made.

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

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

The Lost button will appear and will be the only button available if the page has been marked 'Lost'.

The Final button will be unavailable if the page has any problem fields.

The Incomplete button will be available even if the page has no obvious problem fields. This allows you to flag a record as in need of additional work even DataFax is not aware of what that work is.

The Pending button will be unavailable if the page has advanced beyond new data entry to Incomplete or Final status, unless your permissions include 'Data View - with select'. This permission is typically restricted to study coordinating personnel who may demote problem records to Pending status to exclude them from statistical analyses until the problem is resolved.

4.6. Correcting Key Fields

Each data record has 4 numeric key fields: study, page, assessment and patient. Together they uniquely identify each data record in the study database. It is critical that these keys are correct and typically they will be automatically set to the correct values. But if you discover an error it can be corrected by selecting Change Keys from the Page menu and using the dialog illustrated below.

Page - Change Keys

This page belongs to a different study

Study
Change from 253 to

Page
Change from 003 to 002

Assessment
Change from 1 to

Patient
Change from 16002 to

Reason

OK Cancel

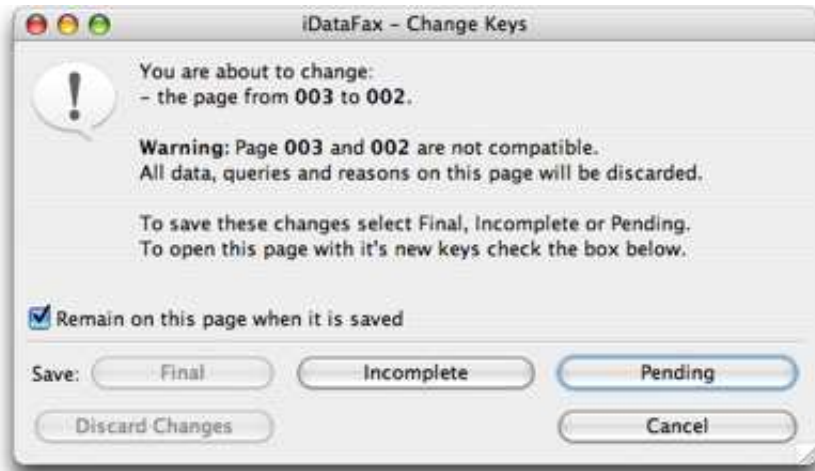
The study number can only be changed if the data record has an image. When the study number is changed all images are sent to the router and the data record is deleted from the current study. It is not possible to move a data record directly to another study even if you have the necessary permissions.

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

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

If **OK** is selected to confirm the change **iDataFax** checks to see if the new plate is compatible with the old one, and also checks to see if a data record with the new keys already exists in the database. You will then be presented with one of the following 4 confirmation dialogs depending on the result of these 2 checks.

No existing record but pages are incompatible



If the new page has different data fields from the old one, the existing data, queries and reasons can not be transferred and must be discarded. If this is the case a warning message is displayed, as illustrated in this dialog.

Click cancel if you do not wish to continue, or one of the Save options: Final, Incomplete or Pending to proceed with the key change.

If you check Remain on this page when it is saved, the page will be opened in it's new location. This is recommended.

No existing record and pages are compatible



In this example, only the patient ID is being changed. Since the pages are the same they will have the same data fields and thus it is possible to transfer the data record to the new keys.

Click cancel if you do not wish to continue, or one of the Save options: Final, Incomplete or Pending to proceed with the key change.

New keys already exist but pages are compatible

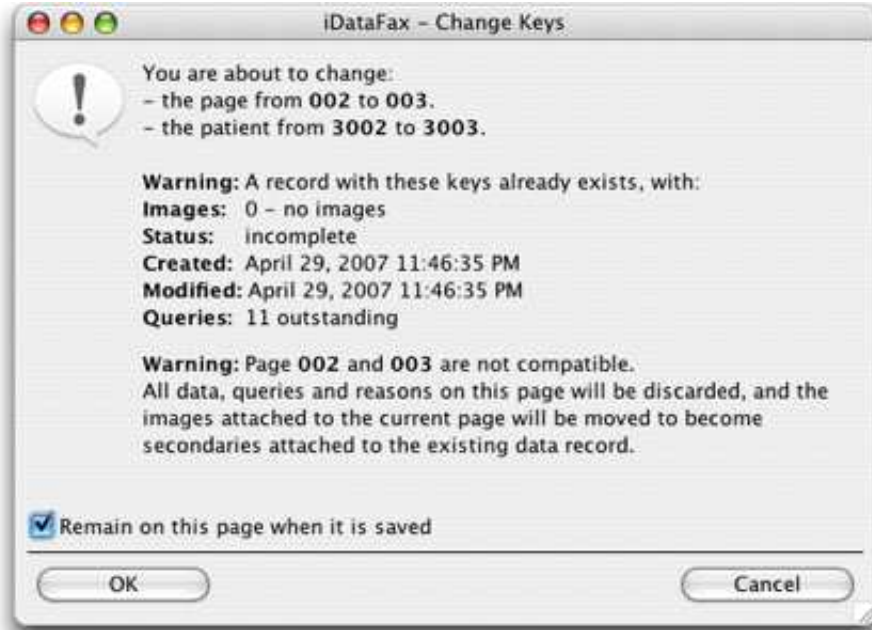


If a data record already exists with the new keys you can either cancel the key change or continue by selecting one of the 2 conflict resolution options.

If you chose to keep the existing primary record it will not be changed in any way, and the current data record with all of it's queries and reasons will be deleted. The only thing that will move to the new keys will be any images from the current page.

If you chose to make the current record primary, it will be moved with all of it's queries, reasons and images to the new keys, and the existing data record with all of it's queries and reasons will be deleted. Only images will be preserved from the existing record and they will become secondary.

New keys already exist and pages are incompatible




If a data record already exists with the new keys, and the data fields on the current page differ from those on the existing page, you can either cancel the key change or continue.

If you chose to continue the existing data record will not be changed in any way. The data on the current page can not be moved because the data fields are different on the new page, thus all data, queries and reasons on the current page will be discarded. The only thing that will move to the new keys will be any images from the current page; and if the existing page already has images, all moved images will become secondary.

4.7. Images of CRFs and other Documents

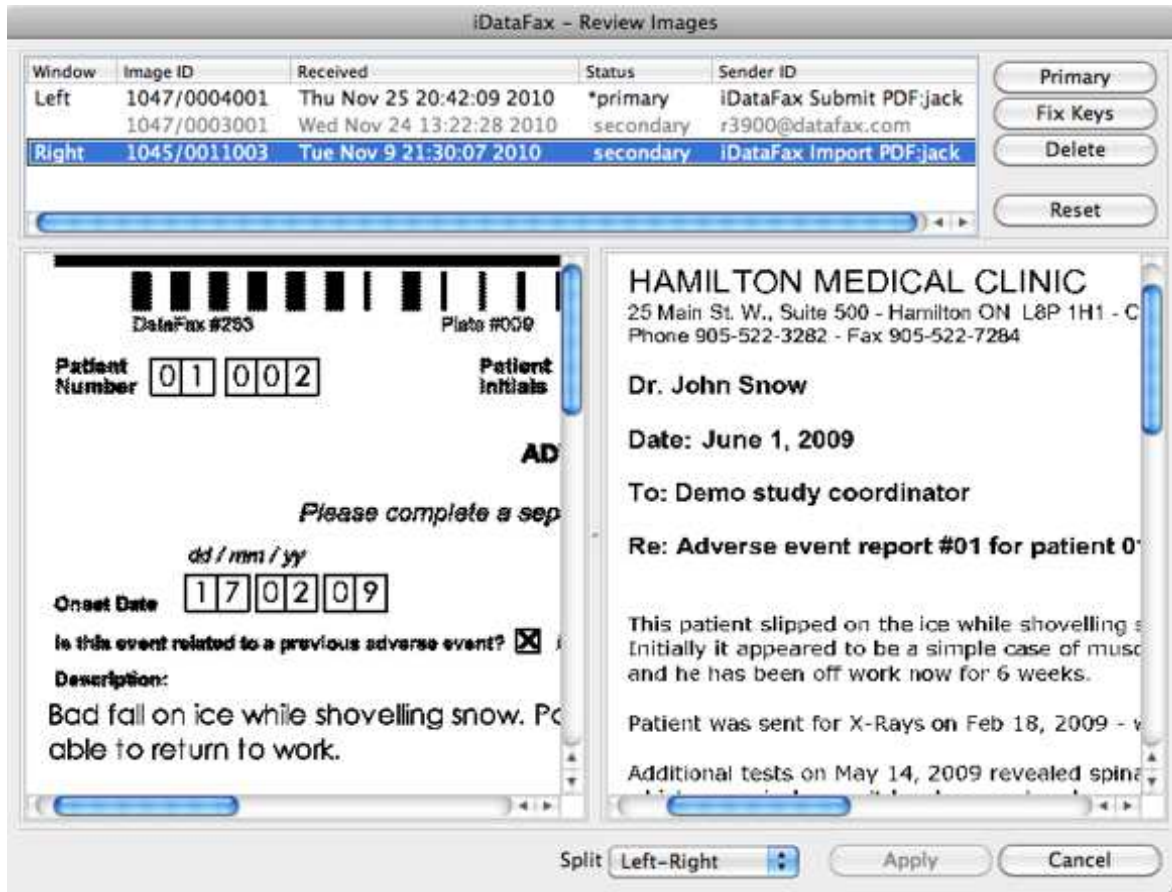
DataFax can receive and link scanned or faxed images to data records. An image could be a faxed copy of the original paper case report form or a supporting source document from medical records. Each image must be linked to one and only one data record.

Multiple images may be linked to the same data record (e.g. all faxed copies of the original CRF page as corrected over time). One image must be designated as the 'primary' copy. This is the image that will appear along with the data record when the screen is split in data and list views. All other images have status 'secondary' and can be reviewed by selecting Page-Review Images or clicking the image count button in Data View.

If one or more images have been linked to the current data record, 2 buttons will appear in the lower right corner of the screen in Data View:  Clicking the button labelled 'i' will toggle the primary image between show and hide. Depending on which option is currently set in User Preferences, the screen will either split to show both the data and image windows, or toggle between showing just the primary image and just the data screen.

The 'i' button is prefixed with another button that shows the number of images linked to the current data record. Selecting this button, or selecting 'Review Images' from the 'Page' menu brings up a dialog, illustrated below, which can be used to review and manage the images.

Page - Review Images



This dialog shows all images linked to the current data record. It shows each Image ID, when the image was received, whether it is the primary (top) or a secondary image, and the Sender ID from the DataFAX server fax log. This dialog can be used to:

- Review Images: Select each image in turn from the image list to display that image.
- Compare Images: The 'Split' button has 3 modes: No, Top-Bottom and Left-Right. When the window is split click on any 2 images in the image list to display them together. Double clicking on one of the images in the image list can then be used to switch them between the 2 display windows.
- Specify the Primary Image: When the dialog opens the primary image is tagged with an asterisk in the image list. Selecting a secondary image and then clicking the 'Primary' button will change that image to primary and demote the original primary image to 'secondary', but the asterisk remains on the original primary image as a reminder of which image was primary when you opened the dialog. Changes in image status do not take effect until the 'Apply' button is selected.
- Delete Images: Selecting an image and then clicking the 'Delete' button will change 'Status' to 'deleted' but this will not take effect until you click 'Apply'. Status can be changed from 'deleted' back to 'primary' or 'secondary' by clicking 'Undelete', but once 'Apply' is selected this is no longer possible. If there is more than one image the primary copy can not be deleted until all secondary images

have been deleted.

- **Fix Keys:** If an image has been linked to the wrong data record you can relink it to the correct record by selecting 'Fix Keys' and then entering the correct patient ID, visit and plate numbers. The image will then be unlinked from the current data record and linked as a secondary image to the new data record. If necessary you can then open the new record to change the image status from secondary to primary.

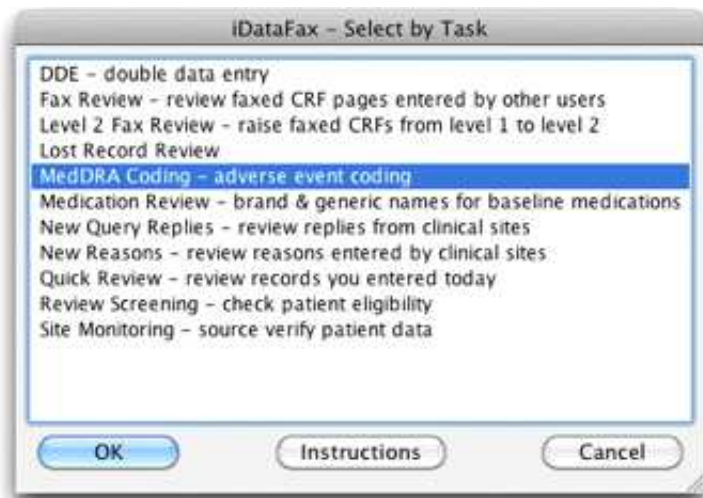
4.8. Working with Tasks

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

4.8.1. Performing Tasks

To perform a task use the Select-By Task menu item to invoke the following dialog.

Select - By Task



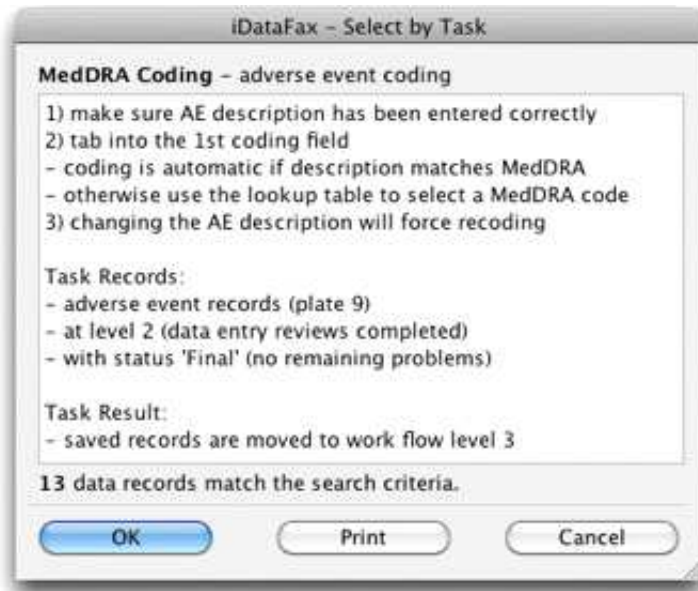
To read the task instructions before launching it select the Instructions button.

To perform a task double click it in the list, or select it and click OK.

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

After selecting a task **iDataFAX** sends a request to the study server to get data records that match the task specifications and then displays the number of records found along with the task instructions as illustrated below.

Task Instructions



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

Instructions will typically include: a description of the record selection criteria, what the user needs to do with each task record, and what happens when a task record is saved.

Selecting OK will retrieve the records that met the task criteria. The record list will include only those sites, patients and visits that contain task records. If user preference 'open first task record when a task set is built' is on, the first task record will open automatically, otherwise a patient binder must be selected to display the task records.

Task Records



The title shows the current patient ID# and the current task record and number of task records for this patient.

The square icon in the title toggles between the standard patient binder list (shown here) and a simple list of task records.

Task records are flagged with the letter 'T' which changes to lower case 't' when the record is saved. The current 't/T' record counts are displayed at the bottom of the **iDataFax** window (not shown).

Use the 'Show All Records for This Patient' button to open the patient binder and review other records for the current patient. Clicking this button again will return to Task Records only.

More than one user can work on the same task at the same time. Each user gets a list of pointers to the records currently available for the task, but a patient binder is locked only when it is opened, and only one user can have the binder locked at a time. Other users will be able to open the binder in view only mode until the lock is released. Thus the next user to open a binder will get the current version of the data records, including any changes made by the previous user.

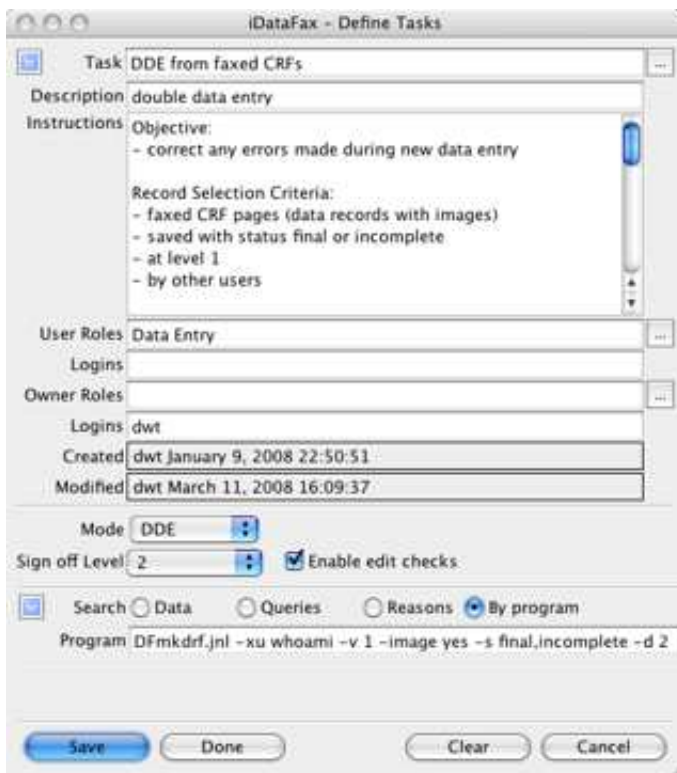
Saving a task record changes the task icon from 'T' to 't', but only for the user who saved the record. Thus if more than one user is working on the same task at the same time, it is possible that the task will have been completed by one user before another user opens the patient binder, and that the second user will thus wonder why the record has been included in the task set. A clue that this may have occurred is provided by the 'Last Save' date/time stamp at the bottom of the screen which may indicate that the record has been modified since the user began working on the task.

When you are finished performing a task use Select-All Records to put the task set away, remove the 'T' and 't' icons from task records, and resume access to all patient binders and data records.

4.8.2. Defining Tasks

Users with permission can define tasks for themselves and other users using the task definition dialog illustrated below. Only one user can define tasks at a time, but other users can open this dialog in view only mode.

Select - Define Tasks



Task name, description and instructions document what the task is about.

User Roles and Logins identify who is allowed to perform the task.

Owner Roles and Logins identify who is allowed to modify the task definition. In addition study administrators have permission to modify all tasks.

Select a mode, the level you want records moved to when they are saved, and whether you want edit checks enabled or disabled while performing the task.

The final section (closed in this example) is for the record retrieval specifications. They can consist of data, query or reason criteria, or any standard DataFAX or custom program that outputs a DataFAX retrieval file.

Multiple user and owner, login and role names may be entered using a comma delimited list, and '*' or 'all' may be entered to specify all login or role names.

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

Modes include the following:

- View - when working in this mode no changes can be made to data or metadata (queries and reasons), and no changes are made to the work flow level.
- Edit - in this mode changes can be made to data and metadata (as permitted by user permissions). New and modified metadata are saved at the current level of the data record, and the level of the data record itself remains unchanged.
- Modify - in this mode the work flow level is changed to the specified sign off level, but only for those data and metadata records that are modified. Thus it is possible for data and metadata records to end up at different levels.
- Validate - in this mode the work flow level of data and all metadata records is changed to the specified sign off level when a Save button (Final, Incomplete or Pending) is selected, regardless of whether or not any changes were made to data or metadata.
- DDE - In double data entry mode the current data values and metadata are hidden until the user exits each data field whereupon the value entered is compared with the current value in the database. If they differ a dialog appears asking the user to select the correct value. The user must tab through all data fields before the record can be saved. On save the data record and all metadata records move to the sign off level. Field-List DDE Status on This Page can be used to check the changes made so far and the data fields that remain to be entered, on the current data record.

Sign off level is a number (1-7) which is stored as a special field (DFLEVEL) in each data and metadata record for work flow management. New data entry is typically saved at level 1. Higher levels are used to signify that some review task has been completed - analogous to moving paper CRFs from one persons inbox to another. In the example above, double data entry is performed by selecting records from level 1 and saving them to level 2. Thus each record will only be double entered once, unless it is returned to level 1 by some event, like a refax.

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

The following examples illustrate how data, query, reason and program criteria are used to define the records to be selected for different tasks.

Example 1 - Search Data records

The screenshot shows the 'iDataFax - Define Tasks' dialog box. The 'Task' field is 'Drug Review'. The 'Mode' is 'Validate'. The 'Sign off Level' is '3' and 'Enable edit checks' is checked. Under 'Search', 'Data' is selected. 'Status' has 'Final' checked. The 'Expression' field contains 'S(MEDNONE) == 0'. Other fields include 'Site', 'Patient ID', 'Assessment', 'Page' (4), 'Level' (2), 'Creation', 'Modification', and 'Pattern'. At the bottom are 'Save', 'Done', 'Clear', and 'Cancel' buttons.

This example illustrates a review task for drugs recorded on CRF page 4 which have reached workflow level 2 with status Final. The expression builder has been used to select records where the 'check if none' data field (MEDNONE) is empty (code 0) because we only need to review pages on which drugs have been recorded.

To be selected records must meet all of the specified criteria. The task is performed in Validate mode with edit checks turned on. On saving each record it will be raised from level 2 to level 3.

Example 2 - Search Queries

Task: New Queries

Mode: Validate

Sign off Level: 2 Enable edit checks

Search: Data Queries Reasons By program

Site: _____

Patient ID: _____

Assessment: _____

Page: _____

Field: _____

Level 1: _____

Creation: _____ By: _____

Modification: _____ By: _____

Resolution: _____ By: _____

Pattern: _____

Detail: Criteria have been specified

iDataFax - Query Detail

Usage: external internal

Type: clarification correction

Status: new, not in QC report in QC report, not sent in QC report, sent
 resolved, not available resolved, not relevant resolved, corrected
 pending

Problem: missing illegal inconsistent
 illegible fax noise missing page
 EC missing page overdue visit other

Last Report: _____

Query Text: _____

Note Text: _____

Reply Text: _____

Done Clear Cancel

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

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

Example 3 - Search Reasons



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

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

As for example 2, this task should also be performed using the Field - Review Queries & Reasons dialog.

The following examples illustrate how tasks can be defined by running a program that generates a DataFax retrieval file as output. DataFax includes 2 standard programs which are designed for this purpose: DFmkdrf.jnl which selects records from the study journal files and DFmkdrf.ec which selects records identified by edit checks. We will only show some examples here. A full description of these programs can be found in the Appendix at the end of this guide. If you need to write a custom program an explanation of DataFax retrieval files can be found in the DataFax Programmers Guide.

Example 4 - Search by Program DFmkdrf.jnl



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

Example 5 - Search by Program DFmkdrf.jnl



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

Example 6 - Search by Program DFmkdrf.jnl

Task Today

Mode Edit

Sign off Level 1 Enable edit checks

Search Data Queries Reasons By program

Program DFmkdrf.jnl -u whoami -t today

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

Example 7 - Search by Program DFmkdrf.ec

Task Edit Checks (Screening)

Mode Validate

Sign off Level 2 Enable edit checks

Search Data Queries Reasons By program

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

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

Example 8 - Search by Program DFmkdrf.ec

Task Edit Checks (Initials)

Mode Edit

Sign off Level 2 Enable edit checks

Search Data Queries Reasons By program

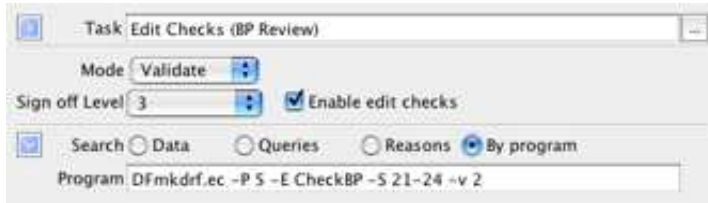
Program DFmkdrf.ec -P 1-102 -E Checkinit

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

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

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

Example 9 - Search by Program DFmkdrf.ec



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

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

4.9. Adhoc Record Selection

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

4.9.1. Changing Mode and Level

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

The default mode, set when **iDataFAX** starts, is Modify and the default sign off level is set to your lowest write level (defined in your study roles). Mode, sign off validation level, and whether edit checks are on or off, are also set whenever you perform a task or build an adhoc task set, but they can also be changed at any time from the Select menu as shown below.

Select - Change Mode & Level



This dialog can be used to change your mode, sign off work flow level, and to enable or disable edit checks, but it is only available to users who have Data with Select permission.

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

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

4.9.2. Select - By Data Fields

Adhoc task sets can be created using the same record selection dialogs already described in the section on defining tasks. As for predefined task sets, the records in an adhoc task set are also flagged with the 'T' and 't' icons. To get started, choose Select: By Data Fields to launch the dialog shown below.

Select - By Data Fields

To be selected a record must meet all of the specified criteria. Criteria that are left blank are irrelevant. In this example, Pages 8 and 9 that are at work flow Level 1 with status Final will be selected for all patients at Sites 1 to 33.

The selected records will be reviewed in Validate mode with a sign off level of 2. Thus, whether or not a record is modified, it will be raised to level 2 if it is saved using one of the Save buttons at the bottom of the screen.

If you select Build Set the dialog will remain open and you will be able to add more records to the adhoc task set by specifying a new set of criteria and again selecting the Build Set button.

Select Done when you are finished building your task set and are ready to review the records.

Searching by: Data, Queries, or Reasons determines whether the search criteria are applied to data records, query records or reason records. For example, when searching for records at level 1 you will get different results depending on whether you are searching for level 1 in data, query or reason records.

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

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

When the user selects **Done** a dialog will appear indicating the number of records in the database that match the selection criteria. The user can then select OK to proceed or Cancel to abort the selection.

If the user decides to proceed the record list is reduced to show only those sites, patients and assessments that contain records in the adhoc task set, and each of these levels is flagged with a 'T' icon. Just as with predefined tasks, the 'T' icon changes to 't' when a task record is saved. This shows that the record has been reviewed but does not necessarily mean that the task has been completed as intended. If the record still meets the selection criteria for the task it will come up again the next time the task is performed. All other sites, patients, assessments and records are hidden, but can be revealed by selecting the button labeled 'Show All Records for This Patient' at the bottom of the record list.



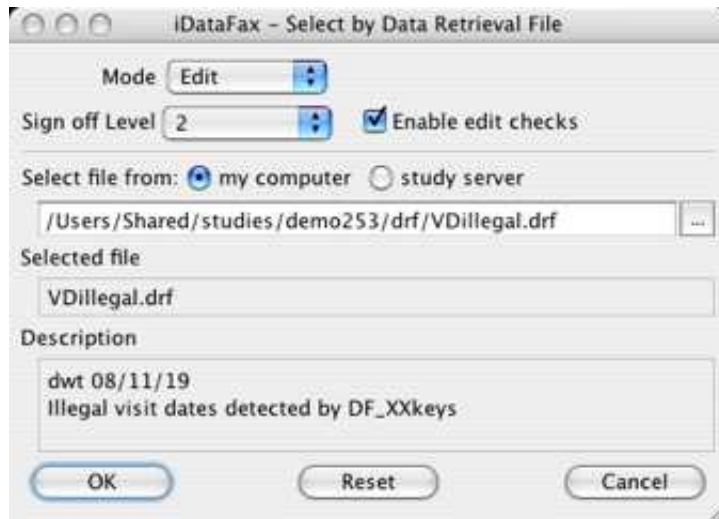
To toggle the current patient between task records and all records use the button at the bottom of the record list labeled Show All Records for This Patient.

The entire record list containing all sites and patients can be toggled using the menu items Show-All Records and Show-Task Records.

4.9.3. Select - By Data Retrieval File

This option can be used to retrieve data records listed in a DataFax Data Retrieval File (DRF). These files must have a .drf extension. They can be loaded from either the study drf folder or the users local PC. DRF files can be created by standard DataFax reports (like the example shown below), by saving a current task set (using File-Save DataFax Retrieval File), by using DFmkdrf.jnl or DFmkdrf.ec (described in the Appendix) or with a custom program.

To retrieve records listed in a DRF choose Select: By Data Retrieval File to launch the dialog shown below.

Select - By Data Retrieval File

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

Edit mode is specified which means that the work flow level of existing data and metadata records will not be changed.

The Sign off level of 2 will only be used for any new queries or reasons that are created during the review.

If the DRF contains a descriptive header it will be displayed in this dialog when the file is selected.

If each record in the DRF includes a description (e.g. explaining why it was included) it will be displayed in the message window at the bottom of **iDataFAX** when a record is selected in the record list. This is optional and may not be present in all cases.

4.9.4. Select - Batch Validate

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

- The user is able to retrieve the records. Records the user does not have permission to get or which are currently locked by another user can not be batch validated.
- Record status is final, incomplete, pending or lost. New records can not be batch validated.
- The records are currently at levels for which the user has modify permission.
- Users can only move records to levels for which they have write permission.

There are 3 options: move the current page only, move all open pages for the current patient, and move all records in the current task set (i.e. records flagged 'T' or 't').

Select - Batch Validate



In this example all open pages for the current patient will be moved to work flow level 3 when the Apply button is selected. The open pages could include assessments opened by: (1) selecting them in the record list, (2) using Patient - Expand All Assessments, or (3) as the result of a predefined or adhoc task.

When the Apply button is selected the specified records are moved immediately. No edit checks are triggered.

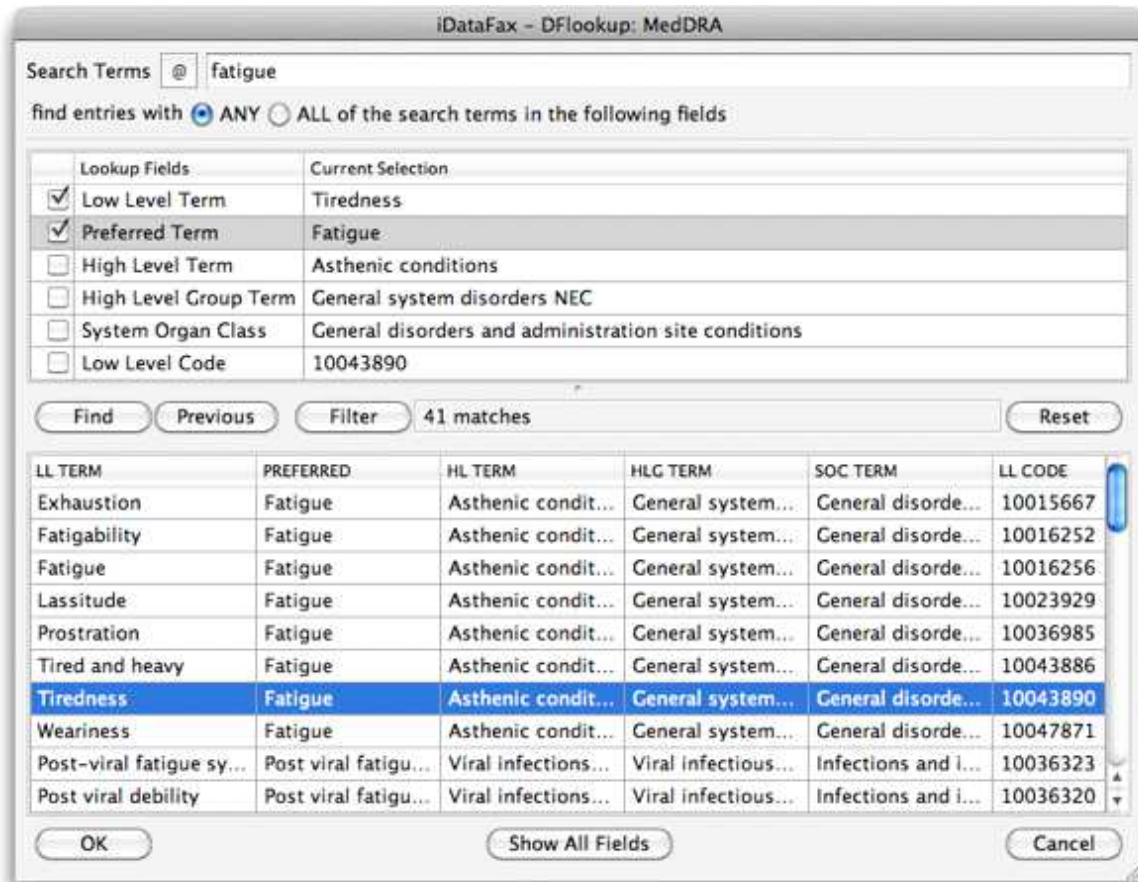
4.10. Using Lookup Tables

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

Regardless of how the edit check is programmed, if a lookup table appears while performing data entry, the user is able to search the lookup table and select one of it's entries (rows), or click the Cancel button to select none of them.

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

Lookup Table Example 1



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

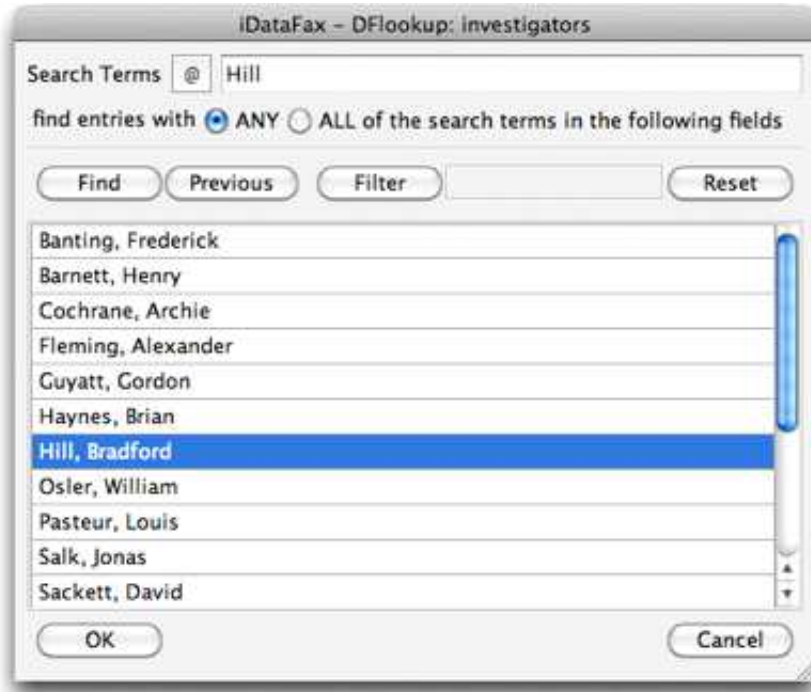
To search for one or more terms enter them in the Search Terms widget at the top of the dialog, check the option to find entries that contain 'ANY' or 'ALL' of the terms, check the fields to be searched, and then click 'Find' or 'Filter'. Find displays the next matching row, while 'Filter' reduces the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

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

When you have found the correct row either double click it, or single click it and then click 'OK'. This will return your selection to the edit check and put the lookup table away. What happens next depends on what the edit check is programmed to do. Typically all or some of the fields from the row you selected will be entered into specified data fields on the current page, but the edit check may be programmed to do something else.

If each row in a lookup table has only one field a simpler dialog will appear without the top field display section. An example appears below.

Lookup Table Example 2



This example shows a simple lookup table in which each row has just one field containing an investigator name.

Apart from its simpler structure this lookup table behaves exactly the same as the MedDRA lookup table described above.

4.11. Query Management

Queries can be created, modified and deleted by edit checks with no user intervention, or manually by selecting 'Add Query', 'Edit Query' or 'Delete Query' from the 'Field' menu to invoke the query dialog illustrated below.

Page - Edit Query

iDataFAX - Edit Query

Site: 1, Patient: 1002, Assessment: Baseline, Page: Patient Entry: 07/01/06

Field: Pulse beats/minute

Reported Value: 044

Problem: Illegal Use: External

Status: New query Type: Correction

Details: Please confirm this very low value.

Note:

Created: dwt November 26, 2008 14:50:32

Modified: dwt November 26, 2008 14:50:32

Resolved:

OK Cancel

The query dialog has the following components:

- **Title.** The title at the top of the dialog shows the information needed to identify which patient and study form the query is about.
- **Field.** The field description, as entered in the study setup, identifies the data field in question.
- **Reported Value.** When a new query is create this field shows the value currently recorded in the data window, but this can be changed by the user. For example, if a date is unclear the user might enter their best guess in the data window but change the query to indicate that the year was unclear like this: Jan ??,2009.
- **Problem.** The problem type can be one of: missing, illegal, inconsistent, illegible, fax noise, and other.
- **Use.** Use can be 'external' meaning the query is to be directed to the clinical site or 'internal' indicating it is for the data management center only.
- **Status.** The status of each query is updated as appropriate to one of the following:
 - **New.** the query addresses a new problem which has not yet been transmitted to the clinical site.
 - **Revised.** the query addresses a revised problem which has not yet been transmitted to the clinical site.
 - **Outstanding.** the query has been transmitted to the clinical site but has not yet been resolved.
 - **Pending.** the site has responded to the query but the reply has not yet been reviewed by the data management office.
 - **Resolved NA.** the query has been resolved - the requested data or correction is Not Available.
 - **Resolved irrelevant.** the query has been resolved - the query was deemed to have been unnecessary.

- **Resolved corrected.** the query has been resolved - the requested correction or information has been received.
- **Type.** Type will be 'Correction' if the query asks for some data correction, or 'Clarification' if the query requests additional information.
- **Details.** A description of the problem and the requested resolution can be entered manually or, if standard queries have been pre-defined, they can be selected by typing a short acronym or using the Details button to select the query from a lookup table.
- **Note.** An internal note, used only by data management staff, can be entered for any internal purpose, such as recording special circumstances explaining why or how a query was resolved.
- **Time Stamps.** The creation time stamp is updated when a query is saved with status "New". The modification time stamp is updated when a query is saved after modification of any of the fields described above. The resolution time stamp is updated when Status is changed to one of the 3 resolution types.
- **OK.** Selecting OK saves the query but it is not transmitted to the study database until the data record is saved.

4.12. Automatic Resolution of Data Queries

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

- Query Use = 'External'
- Query Type = 'Correction'
- Query Problem = 'Missing' or 'Illegal'
- The data field does not have a Reason with status 'Rejected'

If all of the above criteria are met then:

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

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

4.13. Review/Approve Queries and Reasons

Central office review and approval of reasons and query replies can be performed using Field-Review Queries and Reasons or Field-Approve Queries and Reasons which produce the dialog illustrated below.

The dialog looks the same for these 2 options, but they differ in behavior. The 'Review' dialog (shown below) lists all queries and reasons on the current page, while the 'Approve' dialog lists only those queries and reasons with status 'Pending'. Also, when a query or reason is changed from status pending to approved or rejected, it is removed from the 'Approve' dialog but remains visible in the 'Review' dialog.

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

to see the relevant item.

The Review/Approve dialogs are generally used to review and approve new reasons and query replies, but as needed you can also modify or even delete queries and reasons if your permissions allow it. There is one limitation. Changes cannot be made to queries and reasons on 'Pending' level 0 data records as this status indicates the user was interrupted during the entry of a new record and intends to complete it before it is reviewed by study managers.

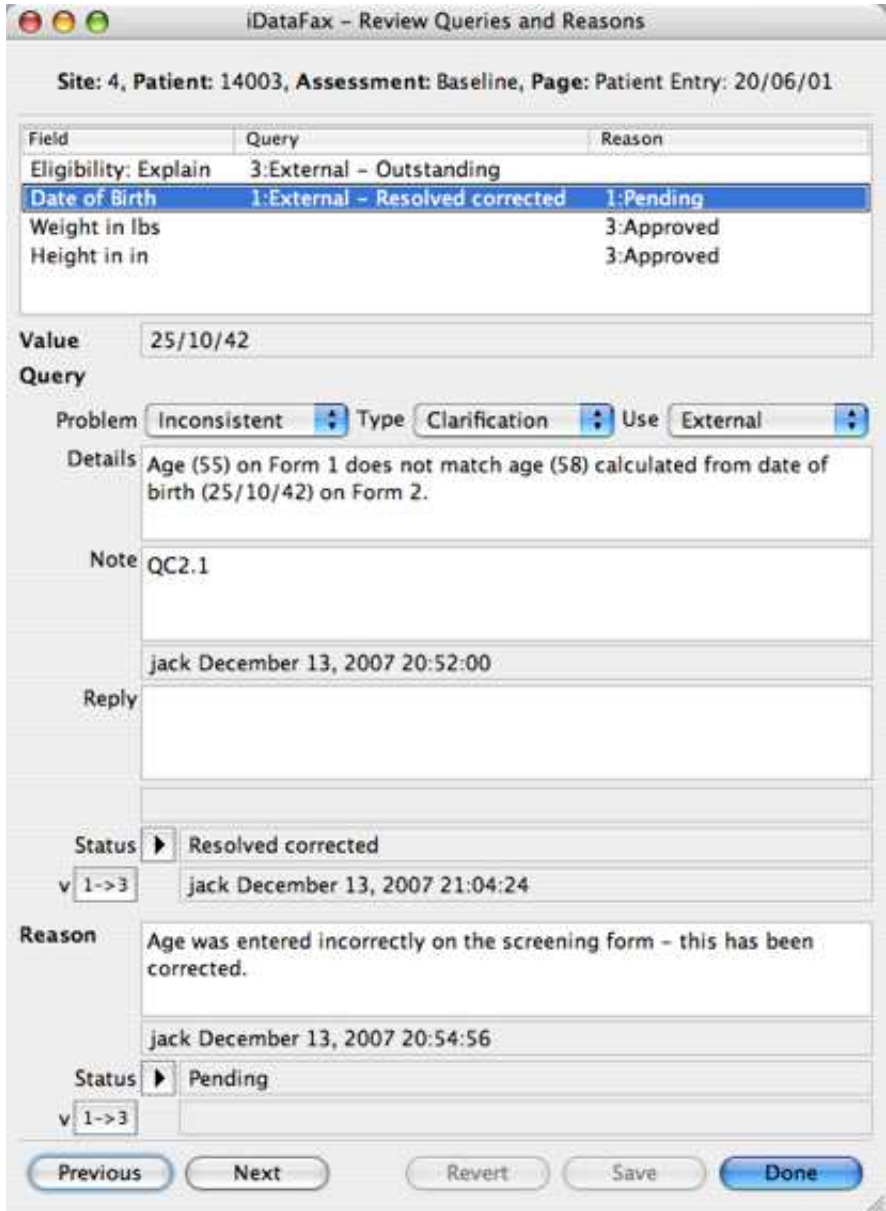
The 2 buttons below Query Status and Reason Status can be used to save your changes to the current query or reason before moving on to the next one, or you can delay saving changes until all queries and reasons on the current data record have been reviewed, in which case an asterisk will appear beside each query and reason with unsaved changes. The Save button at the bottom of the dialog saves the reason and query on the current field simultaneously. The Done button dismisses the Review/Approve dialog without saving any changes.

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

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

The following example illustrates the Review dialog for a data record which has 2 queries and 3 reasons attached to 4 data fields. The data field, and the current work flow level and status of each associated query and reason is shown in the list at the top of the dialog.

Field - Review Queries and Reasons



Date of Birth has a query and a reason, and a current value of 25/10/42. The query (generated by an edit check) was accepted by user jack on December 13, 2007.

Jack corrected a data entry error for age on the screening form and explained this in a reason. He then returned to the Date of Birth field where the edit check found the problem now fixed and thus resolved the query.

The reviewer should change Reason status from Pending to Accepted and save it by clicking the button below Reason status. When this is done the reason level and status will be updated in the list at the top of the dialog.

Saves in this dialog are immediate but only effect queries and reasons; without changing the level of the associated data record.

The Revert button can be used to undo changes to data and metadata on the current field, but only before they are saved.

4.14. Transmitting Scanned CRFs

As an alternative to faxing, CRFs can be scanned to a PDF file, and then transmitted to a DataFAX server as described below. When the server receives the PDF it is processed just like an incoming fax. Thus the pages will not appear in patient binders until they have been reviewed and entered by a user with permission to use 'Fax View'.

**Note**

DataFax also supports emailing a PDF attachment to `datafax@your_server_name`, but unlike email, PDFs transmitted to the server by **iDataFax** are encrypted using SSL and are thus secure.

1. CRFs must be scanned in Black & White and saved as a PDF file. The current version of DataFax does not support color or grey-scale. There is no practical limit on the number of pages that can be included but of course the time required to transmit the file to the DataFax server will increase with its size.
2. Start **iDataFax** and login to the destination DataFax server. Since a PDF is processed just like an incoming fax it doesn't matter which study you are using when you transmit a PDF and the PDF can even contain CRF pages for multiple studies, as long as all pages in the PDF file are for studies that reside on that DataFax server.

**Note**

If you use different DataFax servers for different studies, make sure you select the correct server. Transmitting a PDF to the wrong DataFax server would be the same as sending a fax to the wrong fax number.

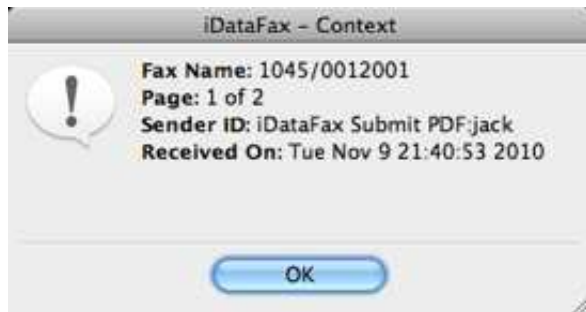
3. Select Submit PDF from the File menu in Data View.
4. This will launch the standard file selection browser on your PC. Use it to select the PDF files you want to transmit.
5. Next you will see a confirmation dialog identifying the DataFax server and each PDF file you selected for transmission. After confirming that these are correct, selecting the Transmit button initiates the transmission, while selecting Quit aborts the operation.
6. You will see a progress bar while each PDF transmission is underway. Pressing the 'Cancel' on the progress bar will not stop the current transmission, but will cancel transmission of any remaining PDFs.
7. When the transmissions are complete the dialog will show the the status of each PDF: 'transmitted', 'failed' or 'canceled'. The 'Continue' button can then be used to select additional PDFs for transmission, and the 'Quit' button ends the dialog.

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

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

PDFs transmitted to the server from **iDataFax** are registered in the DataFax fax log, so the 'Context' option can be used to identify when and how they arrived. Also, just like a fax, the transmitted file is added to the DataFax fax archive.

Page - Context



The Context dialog available in 'Fax' and 'Data' views shows the date and time the page was received by the server along with the method and user, as illustrated here.

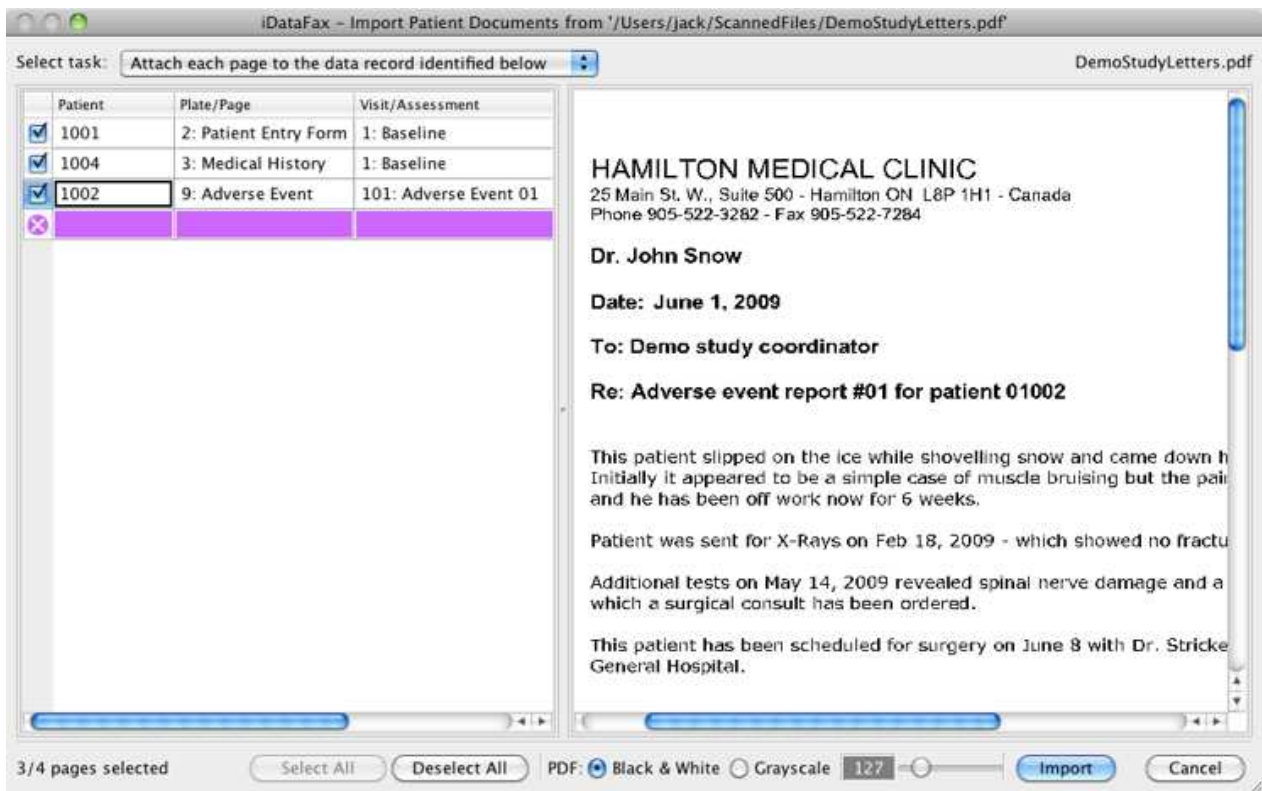
4.15. Importing Patient Documents

Unlike 'Submit PDF', described in the previous section, which sends a PDF to the DataFax server for processing in 'Fax View', users with permission to 'Import patient documents' can import a PDF file and immediately attach each page to the appropriate data record.

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

This feature is launched by selecting 'Import Patient Documents' from the 'Patient' menu in Data View. It first displays the standard file selection dialog, and then when a PDF has been selected, presents the import dialog illustrated below.

The import dialog contains 2 main sections, a window for reviewing the PDF pages on the right, and a spreadsheet for identifying the data records they belong to on the left.



This feature has 3 modes of operation, chosen from the 'Select task' list at the top of the import dialog:

- **Attach all pages to the current data record**

To use this option the destination data record must be opened before 'Import Patient Documents' is selected. When the import dialog appears the keys identifying the current data record will be displayed in the spreadsheet and cannot be changed. Simply select the check box beside each page you want to import, or click the 'Select All' button to select all pages. Then click the 'Import' button. A dialog will appear asking you to re-enter your password. You can still Cancel at this point. If you proceed and enter your password the selected pages will be imported after which a results dialog will appear displaying a summary of the transaction including a list of the pages that were imported.

If the current data record had one or more images before import, all imported pages become secondary images, otherwise the first imported page becomes the primary image and the rest become secondary. The imported images can be reviewed and the primary/secondary classification can be changed using the 'Review Images' dialog, which is selected by clicking on the image count button at the bottom of the screen or by selecting 'Review Images' from the "Page" menu.

- **Attach each page to the data record identified below**

Use this option if the PDF contains pages that belong to a number of different data records. To use this option you must be able to identify the data record that is to receive each page by entering its keys: Patient, Plate/Page and Visit/Assessment, in the spreadsheet.

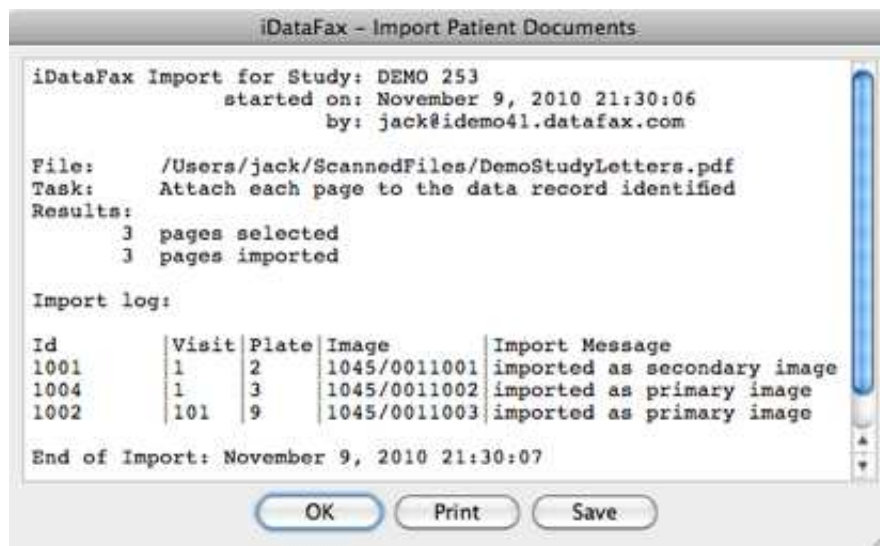
If any of the imported pages are bar-coded to identify where they belong in the patient binders, values for Plate/Page and Visit/Assessment will be read from the bar codes, otherwise enter the appropriate numeric value in the spreadsheet, or right click a cell to use the selection dialog. Enter the Plate/Page number first. The Visit/Assessment selection list will then show only those values that are consistent with that plate (per the study visit map).

To prevent errors **iDataFax** will not allow pages to be imported if they are barcoded with a different study number. Also, users can only import pages for data records which their study permissions allow them to modify. If a key field contains a value that is illegal or not permitted the cell will appear purple and the page selection check box will not be available, unless the problem keys are corrected.

If a page contains a bar code for a different study or the identified record is at a workflow level the user can not modify, a red X replaces the page selection check box indicating that the page cannot be imported.

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

When the pages you want to import have been identified and checked click the 'Import' button and enter your password. Each page will be attached to the specified data record as a primary or secondary image, as described for the previous option. The assignment will be displayed in the results dialog, illustrated below.



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

- **Import data entry worksheets/CRFs identified below**

Use this option if you want to import worksheets or CRFs on which data has been recorded and then use DataFax's split-screen data/image feature to enter the data into the corresponding data records.

This option, begins like the previous one: the pages to be imported are identified and selected, the import button is clicked and the user is prompted to enter their password, after which the selected pages are imported and the results dialog appears. It differs from the previous option as follows:

- Only one page can be imported for each data record. If the same keys are entered in the spreadsheet for a second page, the selection check box will become unavailable for that page.
- Each imported page becomes the primary image for its data record. The previous primary image (if any) becomes secondary.
- **iDataFax** builds a task set of all imported pages, and displays the first task record when the user closes the results dialog. If any of the imported pages did not have a matching data record before

- import, a data record with pending status is created and added to the task set.
- The user then performs data entry by comparing the data fields with the values recorded on the imported CRF or worksheet, and entering or correcting the data fields as needed.
 - All imported pages should be processed before releasing the task set, but if this is not possible they can be saved using 'File-Save Data Retrieval File'. They can then be retrieved and completed another time using 'Select-By Data Retrieval File'.

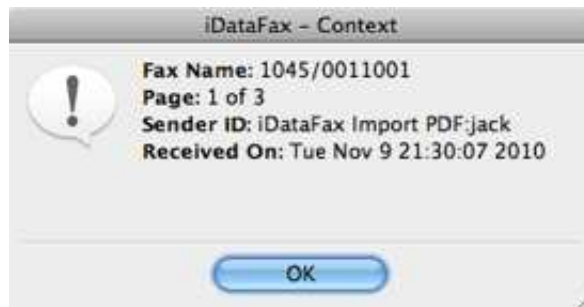
Spread-Sheet Keyboard Short-Cuts

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

Page Context

Pages imported in **iDataFax** are registered in the DataFax fax log, so the 'Context' option can be used to identify when and how they arrived. However, since pages are selected and imported individually, the entire PDF is not copied to the DataFax fax archive the way it is when a fax arrives or a PDF is transmitted by the method described in the previous section.

Page - Context



Images imported from **iDataFax** are identified in the Context dialog with the label "iDataFax Import PDF:username", as illustrated here.

4.16. Data View Menus

This section describes the options available under the menus displayed at the top of the screen. The specific menus displayed, and the availability of options under each menu, will vary depending on user permissions and whether an action is allowed at any given time.

4.16.1. File Menu

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

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

These functions make it possible to modify edit check code, republish it and then reload the edit checks to test the modifications and trace edit check execution as the user enters and exits records and fields. When working in a production study we recommend using DFedits_test and reloading the published test file to avoid disrupting the production edit checks seen by other users.

- Save Data Retrieval File - create a DRF file listing the keys of all records in the current task set. This allows you to reload this same set some time later Using Select-By Data Retrieval File.
- Save As PDF... - create a PDF file containing data and/or images from the current patient binder or task set. Use this option if you want to: print blank CRFs, print fax and data records side by side, or include data records with the same field color coding used in iDataFax.
- Save As Bookmarked PDF... - create a PDF file containing data and/or images from the current patient binder or task set. This option includes many of the same options as the command line program DFpdf and includes a navigation sidebar indexed by patient ID, visit and plate. Use this option to produce a PDF containing any combination of CRF images and data records, to bind specified data fields (e.g. for endpoint adjudication committees), and to password protect the PDF file.

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

- Save Task Set... - create a PDF file containing the data record keys, set creation method, set instructions, user name and date for the current task set.
- Print... - print blank CRF books with patient ID and visit numbers pre-printed, or pages (containing data and/or images) from the current patient binder or task set.
- Print Task Set... - print the data record keys, set creation method, set instructions, user name and date for the current task set.
- Preferences... - this dialog is used to set user preferences. Changes are applied immediately and persist the next time you login.
- Change Password... - allows you to change your **iDataFax** login password.
- New Study... - allows you to return to the login/study selection dialog and either launch a new study session on the current server or launch a new login session. This may be useful if you want to compare data in 2 different studies, compare information presented in different views (e.g. reports and data views) within the same study, or compare behavior for 2 login sessions with different study roles during study setup.
- Close Study - closes your connection to the current study and returns to the study selection window, where a different study may be selected from among those available on the current **iDataFax** server.
- Exit - closes your connection to both the current study and the current **iDataFax** server, and terminates the **iDataFax** program.

4.16.2. Edit Menu

When a field in the data entry window is selected the following Edit menu items become available:

- Undo - Undoes the last edit operation performed
- Redo - Redoes the last edit operation performed
- Cut - Copies the contents of the current field to a buffer, then clears the field
- Copy - Copies the contents of the current field to a buffer
- Paste - Copies any data previously cut or copied to the current field at the current cursor location
- Clear - Removes any data from the current field
- Select All - Selects all data in the current field

4.16.3. Select Menu

The Select menu is used to select patients and data records for review. Selected patients and records are tagged with the letter T (for task).

- All Records - Cancel the current selection criteria and return to the normal display showing all patients and records
- By Task - Select data records using a pre-defined task.
- By Data Fields - Select data records by: site, patient, assessment, page, level, status, etc. as well as by metadata (queries and reasons). This option requires permission for Data - with Select.
- By Data Retrieval File - Select data records using a pre-defined data retrieval file (filename.drf)
- Define Tasks - define tasks for oneself and/or for other users.
- Change Mode & Level - DataFax supports 4 working modes and allows records to be moved to specified work flow levels. The supported modes include:
 - View - when working in this mode users can review patient data but can not make any changes.
 - Edit - in this mode changes can be made (as permitted by user permissions) but the work flow level of all data and metadata remains unchanged.
 - Modify - in this mode the work flow level is changed to the specified sign off level, but only for those data and metadata records that are modified.
 - Validate - in this mode the work flow level of data and metadata records is changed to the specified sign off level when the user selects one of the Save buttons (Final, Incomplete or Pending), regardless of whether or not any changes were made to data or metadata.
- Batch Validate - This option can be used to move a set of selected records to a specified work flow level.

4.16.4. Show Menu

The Show menu is used to determine which patients and data records are listed in the study binder window. The following choices are available:

- All Records - Show all data records, both those included and not included in the current task set.
- Task Records - Show only data records that have been assembled in a predefined or adhoc task using the Select menu options
- All Patients - Show all patient binders
- Potential Patients - Show only empty patient binders
- Enrolled Patients - Show only patient binders that contain data
- Complete to Date Patients - Show only patient binders with complete data for all assessments completed to date
- Incomplete to Date Patients - Show only patient binders containing pages marked Incomplete or Pending

4.16.5. Patient Menu

The Patient menu includes the following options:

- Start New Patient - adds a new patient binder to the current site for a specified patient ID number. Only patient ID numbers which have been predefined as belonging to the current site, are accepted
- Expand All Assessments - opens all assessments in the current patient binder
- Collapse All Assessments - closes all assessments in the current patient binder

4.16.6. Assessment Menu

When an assessment is selected in the patient binder window the following options are available:

- Add New Assessment - some optional patient assessments may be listed in the patient binder, while others may be selected from this menu and added to the current patient binder
- Mark Assessment Lost - if an entire patient assessment is unavailable (e.g. because the patient missed the visit) this option can be used to mark it lost. If a special missed visit report page has been created for the study it will appear and must be completed and saved like any other study page.

If a missed visit report page has not be created for the study a default dialog will appear. In this dialog you must select a reason from the choice list. Additional text can be entered to explain why the assessment will not be completed. All required pages in the assessment will then be marked 'Lost', a 'L' icon will appear on each of these pages in the record list, data entry will be blocked on all of these pages, and the reason will then be displayed in the reason window (bottom left corner of the **iDataFax** window) whenever one of these pages is selected. To enenable data entry on a page the 'Lost' flag must be removed (see below).

If an overdue visit query exists it will be removed when the assessment is marked lost.

- Unmark Assessment Lost - this undoes the previous option if the default dialog was used. If a special missed visit report page has been completed it will remain in the study database, just like any other study record, unless it is deleted.

4.16.7. Page Menu

The Page menu provides the following options for the current page:

- Save - offers the same 3 options provided by the save buttons at the bottom of the window: Final, Incomplete and Pending
- Revert to Last Save - erases all unsaved changes that have been made to the current page
- Review Images - displays all images (primary plus all secondaries) and allows user to: select which image to call primary, delete secondary images, and correct keys on secondary images
- Change Keys - this option allows you to correct any errors in the key fields that might have occurred when a page was saved, including corrections to the study number, patient ID number, assessment number and page number
- Delete This Page - this option is used to delete a data record. When this is done all of the data, queries, reasons and images associated with the record are deleted. A confirmation dialog is displayed, and a reason can be entered to explain why the record is being deleted. Both the delete action and the reason will appear in the audit trail report created by DF_ATmods. Note: permission to use this option is typically tightly controlled.
- Mark Page Lost - if a page is unavailable this option can be used to mark it lost. In the dialog which appears you must select one of the standard reasons or 'other'; additional details explaining why the page was lost can be entered in this dialog.

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

If a missing page query exists it will be removed when the page is marked lost.

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

- Unmark Page Lost - this undoes the previous option, removes any data query that might have been added to the patient ID field, and enables data entry.
- Context - use this option to display the date and time the CRF page arrived (if one exists), and where it came from (if a source identifier was programmed into the transmitting fax machine).
- Show Field Properties - this option displays key properties of all fields defined on the current page, including: name, description, style, need, type, format and legal values.
- List All Outstanding Problems on This Page - lists each field with a problem on the current page including: required fields that are blank, illegal values, outstanding queries and rejected reasons
- List History of All Changes on This Page - runs the DataFax audit trail report DF_ATmods and displays the results in a separate window. The report includes all changes made to data fields on the current page.
- List DDE Status on This Page - this option can be selected at any time during the performance of a double data entry task. It lists the fields that have not yet been entered, and the fields that have been changed from their previous value.

4.16.8. Field Menu

The Field menu provides field-level functions which depend on the state of the current field and the permissions you have been granted by the study sponsor, including:

- Mark Field Missing - used to assign a predefined missing value code to the current field, or to remove a missing value code previously assigned. Missing values may also be selected using the button on the Missing Value metadata window in the bottom left corner of the screen. After applying a missing value code in either of these ways keyboard shortcut Control+M can be used to apply the same missing value code to other data fields.
- Revert to Last Save - used return the current data field to the state it was in when the page was opened; this includes both the value of the field itself as well as the existence and value of any reasons and queries associated with the field
- Add Reason for Data Value - used to explain the current data value. The reason dialog can also be invoked by pressing the button on the Reason metadata window in the bottom left corner of the screen
- Delete Reason for Data Value - used to delete the reason on the current data field (note: permission to use this option is typically tightly controlled)
- Reply to Query - used to reply to an unresolved query on the current field. The reply dialog can also be launched by selecting the button on the Query metadata window in the bottom left corner of the screen. Some queries can be resolved by correcting the data field and do not require a direct reply. If the study coordinating center wants a direct reply to the query, the phrase (reply required) will appear at the top of the Query metadata window
- Add Query - used by the study coordinating center to add a query to the current data field
- Edit Query - used by the study coordinating center to modify a query on the current data field
- Delete Query - used by the study coordinating center to remove a query from the current data field
- Approve Queries and Reasons - used by the study coordinating center to approve or reject pending reasons and query replies, on the current page
- Review Queries and Reasons - used by the study coordinating center to review all reasons and

queries (resolved and unresolved) on the current page

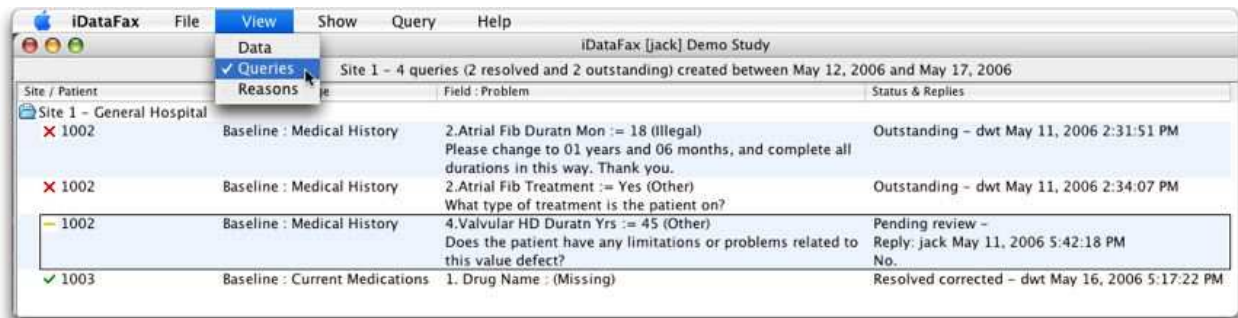
- Show Field Properties - this option lists all properties defined on the current data field, including: name, description, style, need, type, format, legal values, edit checks, etc.
- List History of All Changes on This Field - runs the DataFax audit trail report DF_ATmods and displays the results in a separate window. The report includes all changes made to the data field which currently has the focus.

4.16.9. Help Menu

The Help menu launches the help viewer application and displays information about **iDataFax**. It includes:

- Topics - launches the online user guide
- Color Coding - displays a summary of the colors used and their meaning
- Task Instructions - displays the instructions for the current task (if any)
- Show Roles - lists the role(s) the user plays in the current study
- About iDataFax - displays version and copyright information

Chapter 5. The Queries View



The Queries View is used to review questions from the study coordinating center.

5.1. The Queries Table

As illustrated above, each query is identified by the patient ID number, assessment and page on which it occurs. Under the heading Field : Problem the data field is identified along with its current value and the problem type (in brackets). If necessary, this may be followed by a description of the problem or a question from the study coordinating center. The last column shows the current status of each query, when status was set and by whom, and the current reply made to the query (if any).

Each query is marked with a symbol that shows its current status: a green check mark for resolved queries, a red x for queries that are outstanding, and a yellow dash for pending queries (i.e. where someone has responded to the query but the response has not yet been reviewed by the study coordinating center).

When a query is selected, a bounding box is displayed around it, as illustrated above for the 3rd query in the table.

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

When you are finished with the data field in Data View the quickest way to return to Queries View is to use the Return to Query View button located at the bottom of the record navigation list on the left side of the screen.

5.2. Query Status

Query status has one of 3 possible values:

- Outstanding - the query still needs to be addressed
- Pending - the query has been addressed and is waiting for someone at the study coordinating center to review it
- Resolved - the problem has been solved. This may occur automatically, as when a legal value is entered into a field that has a query of problem type 'missing' or 'illegal'. Or a query may be resolved by someone at the study coordinating center. Query resolutions are classified in one of 3 ways:
 - resolved corrected - always the desired solution

- resolved NA - the requested data/information is just not available
- resolved irrelevant - it was an unnecessary query to begin with

5.3. Queries View Menus

This section describes the options available under the menu labels: File, View, Show, Query, and Help, which appear at the top of the screen. The File, View and Help menus are the same across all views and have already been described above for the Data view. Show and Query are the only menus containing options specific to the Queries view.

5.3.1. The Show Menu

The Show menu is used to select the queries to be displayed in the queries table. The following options are available:

- All Queries - show all queries
- Outstanding Queries - show queries that still need to be addressed
- Resolved Queries - show queries that have been resolved
- Pending Queries - show queries that are awaiting central office review
- Overdue Visit Queries - show outstanding queries for assessments that are overdue
- Missing Page Queries - show outstanding queries for pages that need to be completed
- Data Correction Queries - show outstanding queries that request data corrections
- Data Clarification Queries - show outstanding queries that require a detailed reply
- Outstanding Queries Created in the Past - show outstanding queries added in the past 5, 10, 15, 20, 25 or 30 days
- Outstanding Queries Created More Than - show outstanding queries that are older than 5, 10, 15, 20, 25 or 30 days
- Search Queries - displays a dialog used to search for queries with specified properties as illustrated below.

Show - Search Queries

- To be selected a query must match all of criteria specified in this dialog and the user must have permission to view it. Criteria left empty are irrelevant to the search.
- If the Filter option is selected clicking the Find button reduces the query list to queries that match the search criteria, and the search dialog closes.
- Otherwise search direction (up or down) is used to find the first match starting from the top of the list or from the currently selected query and the Find button changes to Find Next.
- Searching for a text match in the query, note and reply fields is case insensitive unless the match case option is selected.

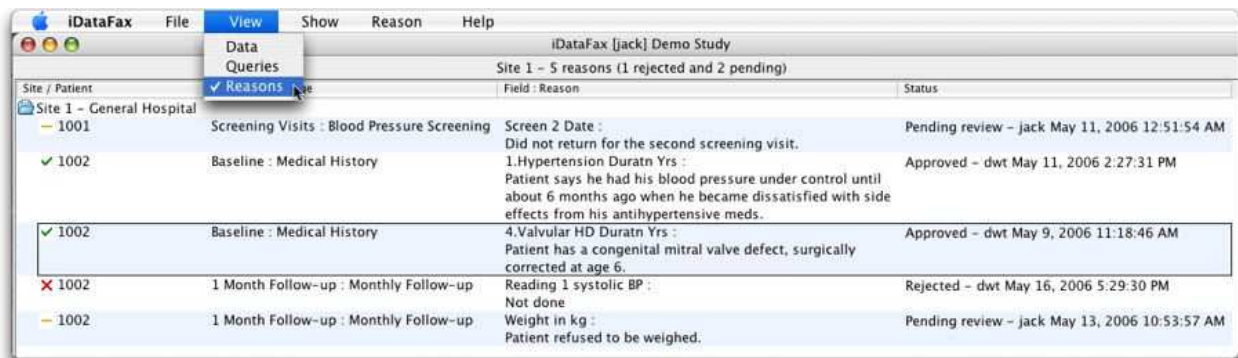
5.3.2. The Query Menu

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

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

To return to the queries table after reviewing a query in the Data view, select View > Queries.

Chapter 6. The Reasons View



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

6.1. The Reasons Table

As illustrated above each reason is identified by the patient ID number, assessment, and page on which it occurs. Under the heading Field : Reason, the data field is identified, followed by the reason that was entered to explain the current value. The last column shows the current status of each reason, when the status was set, and by whom.

When a reason is selected a bounding box is displayed around it, as illustrated above for the 3rd reason in the table.

6.2. Reason Status

Reason status has one of 3 possible values:

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

6.3. Reasons View Menus

This section describes the options available under the menu labels: File, View, Show, Reason, and Help, which appear at the top of the screen. The File, View, and Help menus are the same across all views and have already been described for the Data view. Show and Reason are the only menus containing options specific to the Reasons view.

6.3.1. The Show Menu

The Show menu is used to select the reasons to be displayed in the reasons table. The following options are available:

- All Reasons - show all reasons
- Approved Reasons - show reasons that have been approved by the study coordinating center
- Rejected Reasons - show reasons that have been rejected by the study coordinating center
- Pending Reasons - show reasons that are awaiting central office review
- Search Reasons - displays a dialog used to search for reasons containing specified text strings

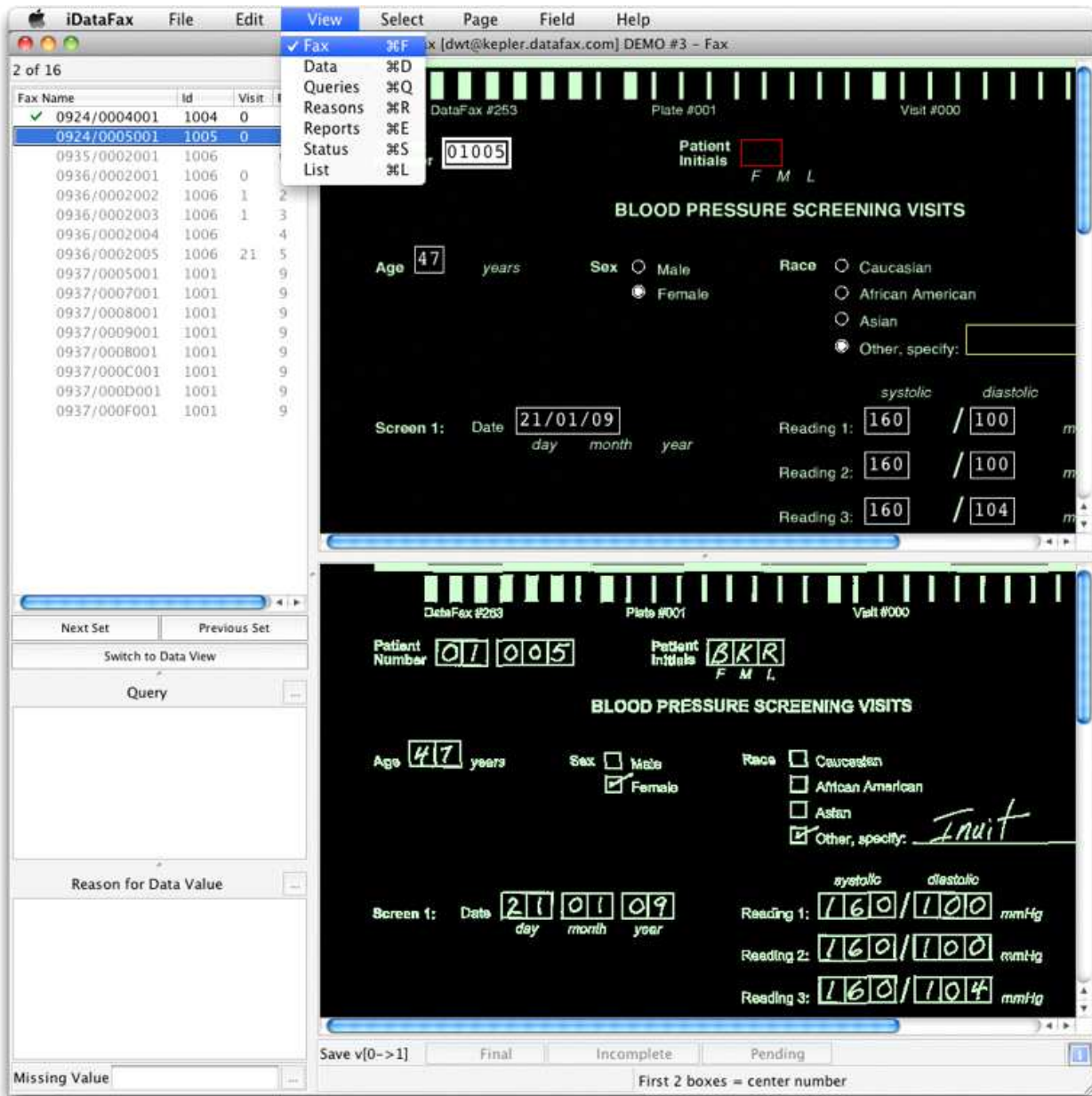
6.3.2. The Reason Menu

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

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

To return to the reasons table after reviewing a reason in the Data view, select the Return to Reason View button located at the bottom of the record navigation list on the left side of the screen.

Chapter 7. The Fax View



Fax View, illustrated above, can be used to enter new data records from paper case report forms (CRFs) that have been faxed or emailed to the DataFax study server, or to enter new data records from hardcopy CRF pages you have in hand and do not plan to fax into the system.

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

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

Use the Tab or Return key to move forward through the data fields, and Shift-Tab or Shift-Return to move backwards. This will ensure that you trip all field entry and exit edit checks designed to assist data entry. When necessary the 2 screens will scroll together to show the same data fields in the data and CRF windows. Occasionally you might also want to use Control-T or Control-B to scroll the CRF image screen by itself to the top or bottom respectively to check something that has scrolled by. Alternatively, if you have a large monitor the screen can be split vertically to display a full page on each side (see File-Preferences).

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

If you have a stack of CRF pages that need to be entered but not faxed into DataFax you can use Fax View in Raw Data Entry mode to enter these pages or use Data View to perform the same task. The only difference is that data entry in Data View is performed within one patient binder at a time, while Fax View allows you to work outside of the patient binders.

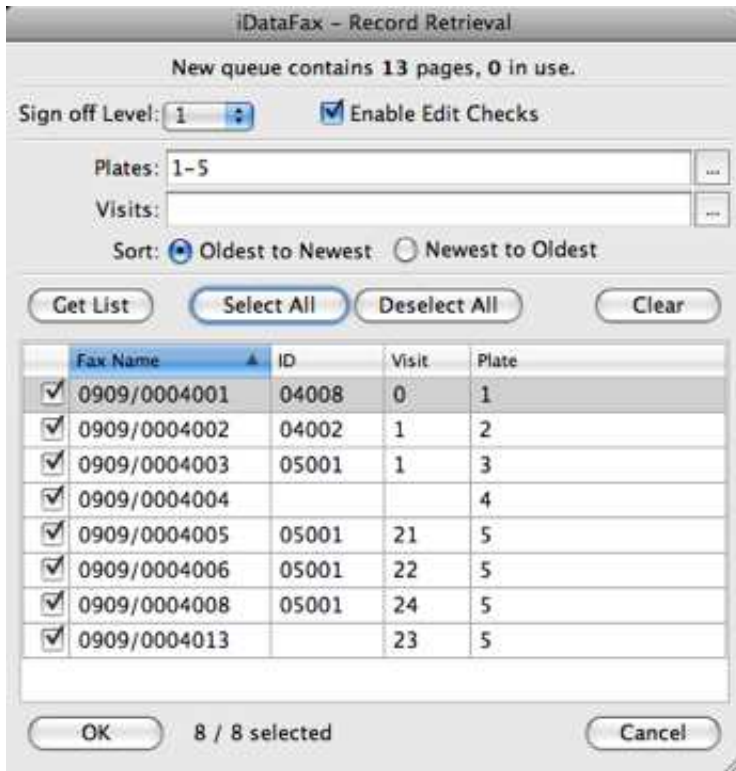
New records are typically saved to the study database at work flow level 1 but it is possible to save new records directly to other levels. Fax View is typically used only by data entry staff at the study coordinating center; this option is not normally made available to clinical sites.

7.1. The Record Selection Dialog

Fax View supports 4 options under the Select menu for building a set of records to be entered. These include: 'Automatic Retrieval' and 'Manual Retrieval' for entering data from faxed CRF pages, 'Raw Data Entry' for entering data from hardcopy CRF pages held outside of DataFax, and 'By Task' which applies automatic record selection rules which have been predefined for a particular user or study role using the 'Define Tasks' menu option.

'Manual Retrieval' allows the user to cherry-pick records from the list of faxed pages awaiting data entry, or search for records with specified plate and/or visit numbers as illustrated in the following example.

Select - Manual Retrieval



Since plates 1-5 were specified only these plates were listed when the 'Get List' button was selected.

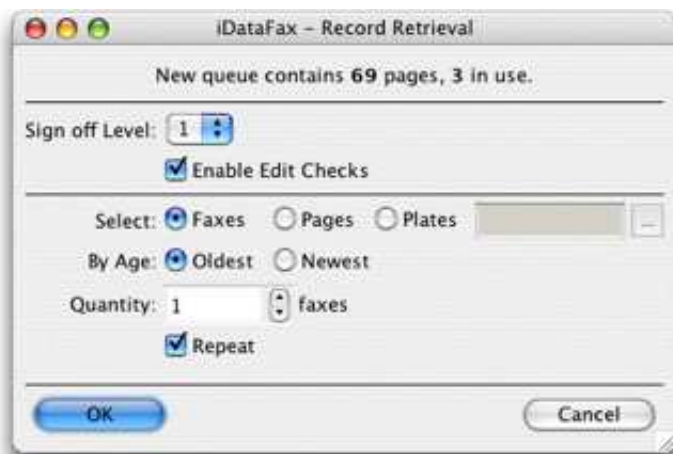
If ICR was able to read the key fields (ID, Visit and Plate) they will appear beside each fax page name (yyww/ffffppp, where yy=year, ww=week, ffff=fax, ppp=page).

Records can be selected individually using a mouse click to select one record and Shift-click to select all records between the last selection and the Shift-click record, or all records can be selected using 'Select All' as shown here.

Finally, to assemble the selected records click 'OK'.

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

Select - Automatic Retrieval



The current status of the new record queue is updated and displayed at the top of Record Retrieval dialog each time it is opened. In this example there are 69 CRF pages awaiting data entry of which 3 are currently locked by other users.

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

'Raw Data Entry' is used to build a specified set of blank data entry screens for data entry from hardcopy residing outside the DataFax system.

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

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

Two examples are illustrated below.

Select - Raw Data Entry (example 1)

The screenshot shows a dialog box titled "iDataFax - Raw Data Entry". It contains the following fields and controls:

- Sign off Level: 1 (dropdown menu)
- Enable Edit Checks:
- Patient IDs: 55034-55039 (text field)
- Assessments: 0 (text field with a browse button "...")
- Plates: 1-2 (text field with a browse button "...")
- # of Cases: 1 (spin box)
- OK (button)
- Cancel (button)

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

Select - Raw Data Entry (example2)

The screenshot shows a dialog box titled "iDataFax - Raw Data Entry". It contains the following fields and controls:

- Sign off Level: 1 (dropdown menu)
- Enable Edit Checks:
- Patient IDs: (empty text field)
- Assessments: 0 (text field with a browse button "...")
- Plates: 1 (text field with a browse button "...")
- # of Cases: 100 (spin box)
- OK (button)
- Cancel (button)

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

Select - Define Tasks

To define a new task select 'New Task' from the 'Task' button and then complete the task definition dialog. This example shows a task created by 'jack' for users with the 'Data Manager' role. Since jack owns the task only he can modify it.

Users can not enter records in Fax View for which they do not have permission. However it is possible for a user to select a fax image for which ICR failed to read the keys and then on entering the keys to discover that they can not save the record. Also if ICR misread the keys a user with limited permissions may be prevented from seeing a page they should see in the list of faxed pages. These limitations argue against giving the clinical sites access to Fax View, except perhaps for Raw Data Entry only.

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

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

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

7.2. Entering New Records

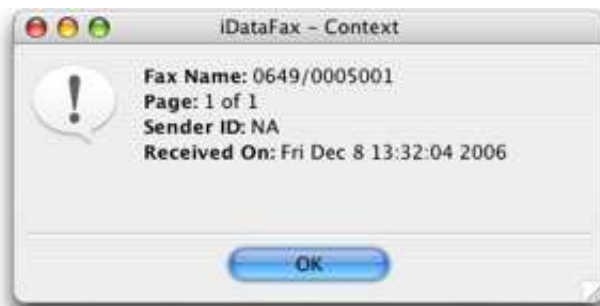
Data entry is performed as already described for the Data View. The main difference is that ICR will have already completed many of the data fields and thus the task is to compare the ICR reading with what was written on the CRF page, and to correct any ICR errors and enter any text fields (which are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

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

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

If you need to know when a CRF page arrived or where it came from select Context from the Page menu.

Page - Context



In this example the current CRF page is page 1 of a 1 page fax. The Sender ID must be programmed into the sending fax machine; if not it will be displayed as NA (not available). The Fax Name is a unique identifier created by DataFax for each CRF page.

7.3. Entering Refaxed CRFs

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

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

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

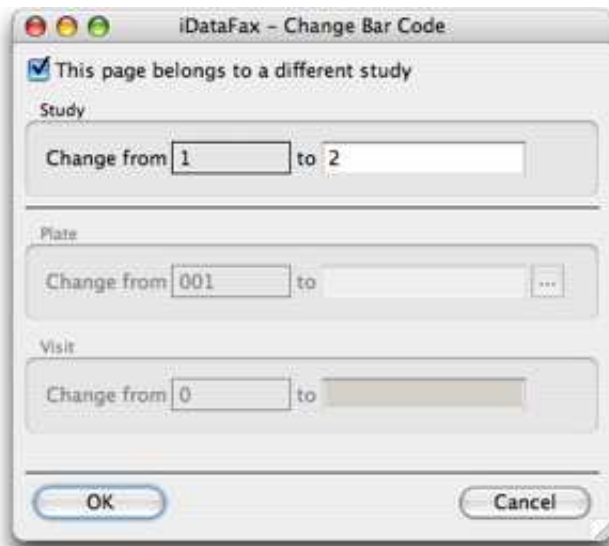
If after loading the existing data record you discover that you have made a mistake select Page - Revert to Initial State to undo all changes to the current record.

7.4. Correcting the Keys

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

If ICR has misread a patient ID or visit number data field, they can be corrected by modifying the data field, but to correct those keys that appear in the bar code you need to select Change Bar Code from the Page menu and use the dialog illustrated below.

Page - Change Bar Code



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

7.5. Switching to Data View

While entering new records you can open the current patient binder to review and/or modify other records, using the Switch to Data View button at the bottom of the record list. Before switching to Data View you will be asked if you want to save or discard any changes you have made to the current Fax View record. The patient binder will then open to the current Fax View record in Data View. This record will be tagged with the letter T in the record list to identify it as the current Fax View task record. This record can not be modified while in Data View, and will display: View only: record in use by Fax view in the message window at the bottom of the screen. The switch button, now labeled Switch to Fax View, can be used to return to

the current Fax View record, and continue with data entry, when you are finished reviewing other records in Data View.

7.6. Record Locking in Fax View

Each set of CRF pages retrieved using the 'Automatic' or 'Manual' method is locked by the user who selects them. This is a lock on the image ID, not on the keys, which may at this point be blank or incorrect. These image locks prevent other users from trying to enter the same new pages in Fax View. In large studies, with 100s of pages arriving each day and several users working together to perform new data entry, it is best to minimize the number of faxes or pages that each person retrieves at a time. We recommend getting 1 fax at a time.

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

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

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

If the patient ID lock can not be obtained the user can still switch to Data View in View Only mode. However, because the record level database lock was released it is possible that when you return to Fax View you will find that you can not continue with data entry because someone else now has the database lock for that record.

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

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

7.7. Fax View Menus

This section describes the options available under the menu labels Select and Page, which appear at the top of the screen. Only those options which are unique to Fax View are included. All other menus and options are the same as already described for Data View.

7.7.1. The Select Menu

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

- Automatic Retrieval - as described above this dialog is used to specify how records are assembled for data entry.
- Manual Retrieval - use this option to display the list of records awaiting data entry and manually select those you want to enter next.
- Raw Data Entry - use this option to build a set of blank records for data entry from hardcopy CRF pages held outside of DataFax.
- By Task - this option allows users to select a predefined new data entry task.
- Define Task - use this option to specify a task for new data entry, including: record selection rules, grant users/roles permission to use the task, user instructions, etc.
- Next Set - this option applies the current record retrieval specifications to assemble the next set of records for new data entry.
- Previous Set - this option allows users to return to the previous set of records, but only records still remaining in the new queue will be displayed; any already entered or now in use by other users can not be accessed.

7.7.2. The Page Menu

The Page menu includes the following options:

- Save - this menu item has pull rights for 'Final', 'Incomplete' and 'Pending' which are equivalent to saving changes using the buttons at the bottom of the screen.
- Revert to Initial State - undoes all changes to the data, queries and reasons on the current page.
- Review Images - this option is used to review all of the images attached to the current data record, and is only available if the current record has more than one image.
- Change Bar Code - as described above this dialog is used to make corrections to the values of bar coded key fields.
- Delete This Page - this option deletes the current image from the new fax queue. It can not be undone within **iDataFax** but is reversable by a DataFax administrator.
- Context - this option shows the arrival date and time, and fax sender ID of the current CRF page
- List All Outstanding Problems on This Page - lists each field with a problem on the current page including: required fields that are blank, illegal values, outstanding queries and rejected reasons
- List History of All Changes on This Page - runs the DataFax audit trail report DF_ATmods and displays the results in a separate window. The report includes all changes made to data fields on the current page.

Chapter 8. List View

8.1. Introduction

In Data View only one data record is displayed at a time, but in List View all data records for a selected CRF page can be reviewed in a spreadsheet where each row is a data record and each column is a data field. This view is useful for comparing data records, searching for particular values, or scanning for data problems. Outlier values can be identified by sorting the spreadsheet on any column - just click on the field name at the top of the column.

As in Data View, the cells in the spreadsheet can be color coded to identify: illegal values (red), outstanding queries (blue), pending reasons and query replies (orange), approved reasons and query replies (green), and blank optional fields (yellow). Queries, reasons and missing value codes are displayed in the lower left corner when a cell is selected that has these attributes; and any images associated with a data record can be reviewed when a record with images is selected.

Unlike Data View, List View does not support data entry, but double clicking any cell in the table will switch to that data field in Data View where changes can be made. Selecting the Return to List View button in Data View will take you back to the original cell in List View. Any changes that were made to the data record, or to its queries and reasons, while in Data View will be displayed when you return to that record in List View.

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

As in all other views what you see and what you can do will depend on your user permissions, which may be different for each DataFax study.

Figure 8.1. View - List

The screenshot displays the iDataFax application window. The top menu bar includes File, Edit, View, Select, Show, Page, Field, and Help. The 'View' menu is open, showing options like Fax, Data, Queries, Reasons, Reports, Status, and List. The main window shows a data table with columns: ID, PINIT, EDATE, ELIG, ELIGEX, BDATE, WTKG, WTLB, HTCM, HTIN, PULSE, SMOKE, and EXERCISE. Below the table is a 'Patient Entry Form' for patient 02007 with initials TIF, showing eligibility criteria and a 'view mode' button.

ID	PINIT	EDATE	ELIG	ELIGEX	BDATE	WTKG	WTLB	HTCM	HTIN	PULSE	SMOKE	EXERCISE
1006	BDS	02/01/11	2		07/10/54	076.0	167.5	183	072.0	046	1	3
004												
2005	NNN	22/12/10	2		05/06/32	070.5	155.5	170	066.9	092	3	2
2006	PWR	10/09/10	2		06/07/40	065.5	144.4	180	070.9	070	4	4
5	02007	TIF	11/11/10	2	12/06/40	083.2	183.5	208	082.0	068	2	1
6	02008	POP	08/06/10	2	04/05/31	060.5	133.3	175	068.8	067	1	1
7	02009	QWE	11/09/10	2	12/07/50	070.5	155.5	166	065.4	059	2	3
8	02011	JOK	19/08/10	2	13/05/33	080.3	177.0	197	077.7	069	2	2
9	11002	BBB	15/01/11	2	14/03/85	070.0	154.3	185	072.8	070	1	1
10	13002	ABC	02/01/10	2	01/01/60	150.0	330.7	150		031	1	1
11	15001	JRF	02/01/11	2	19/03/74	064.4	140.0	168	066.0	056	1	3
12	15002	JMP	05/12/10	2	04/10/70	067.0	147.8	175	068.9	052	3	2
13	15003	RTW	01/03/11	2	02/01/64	070.5	155.5	174	068.5	055	2	1
14	15004	TYR	02/02/11	2	03/03/55	072.6	160.0	160	063.0	051	4	1

8.2. User Preferences

The List View section of the Preferences dialog, available under the File menu, can be used to customize the appearance of List View. Preferences can be used to turn field color coding and text expansion on or off, determine whether field codes or code labels are displayed, select column labels (generic or unique field names, and field number), and select the display format for date fields. All selections made in the preferences dialog are study specific and will be retained across iDataFax sessions.

8.3. Navigation

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

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

The keys [patient ID, assessment, page] of the current record and the number of data records in the table are always visible in the upper left corner of the screen. The work flow level at which the current record was last saved appears along with the date and time at the bottom of the screen. If a Help message has been defined for the current data field it will be shown in the help message window at the bottom of the screen, to the right of the Last Save date.

8.4. Working on a Task

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

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

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

8.5. Selecting Data Fields

To select a subset of the data fields on the current plate, select Select-Field Selection and use the dialog illustrated below.

Select - Field Selection

Field	Generic Name	Unique Name	Description	Type	Format	Legal Values
<input checked="" type="checkbox"/> 7	ID	ID001	Patient Number	number		1001-99999
<input type="checkbox"/> 8	PINIT	PINIT001	Patient Initials	string		
<input type="checkbox"/> 9	AGE	AGE	Age	number		16-79
<input type="checkbox"/> 10	SEX	SEX	Sex	choice		1,2
<input type="checkbox"/> 11	RACE	RACE	Race	choice		0,1,2,3,4
<input type="checkbox"/> 12	RACEOTH	RACEOTH	Race Other, spec...	string		
<input checked="" type="checkbox"/> 13	S1DATE	S1DATE	Screen 1 Date	date	dd/mm/yy	01/01/01-today
<input checked="" type="checkbox"/> 14	S1SBP1	S1SBP1	Screen 1 Read 1 ...	number		60-300
<input checked="" type="checkbox"/> 15	S1DBP1	S1DBP1	Screen 1 Read 1 ...	number		30-150
<input checked="" type="checkbox"/> 16	S1SBP2	S1SBP2	Screen 1 Read 2 ...	number		60-300
<input checked="" type="checkbox"/> 17	S1DBP2	S1DBP2	Screen 1 Read 2 ...	number		30-150

Select all fields Deselect all fields

Fields can be selected or hidden using the check box beside each field, and reordered by selecting a field and then moving it up or down using the arrow buttons at the bottom of the field list.

8.6. Searching Data Records

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

The Search dialog can also be used to put data records from the current plate into a 'Task' set. After entering the record selection criteria selecting the New Task button will display a task confirmation dialog (where the user can set Mode and Edit Checks options) after which the selected records will be flagged with the 'T' icon to show that they belong to a new task set. The Add to Task button will then become active and can be used, after entering a new set of record selection criteria, to add more records to the current task set. This can be repeated as needed to build a task set.

Select - Search

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

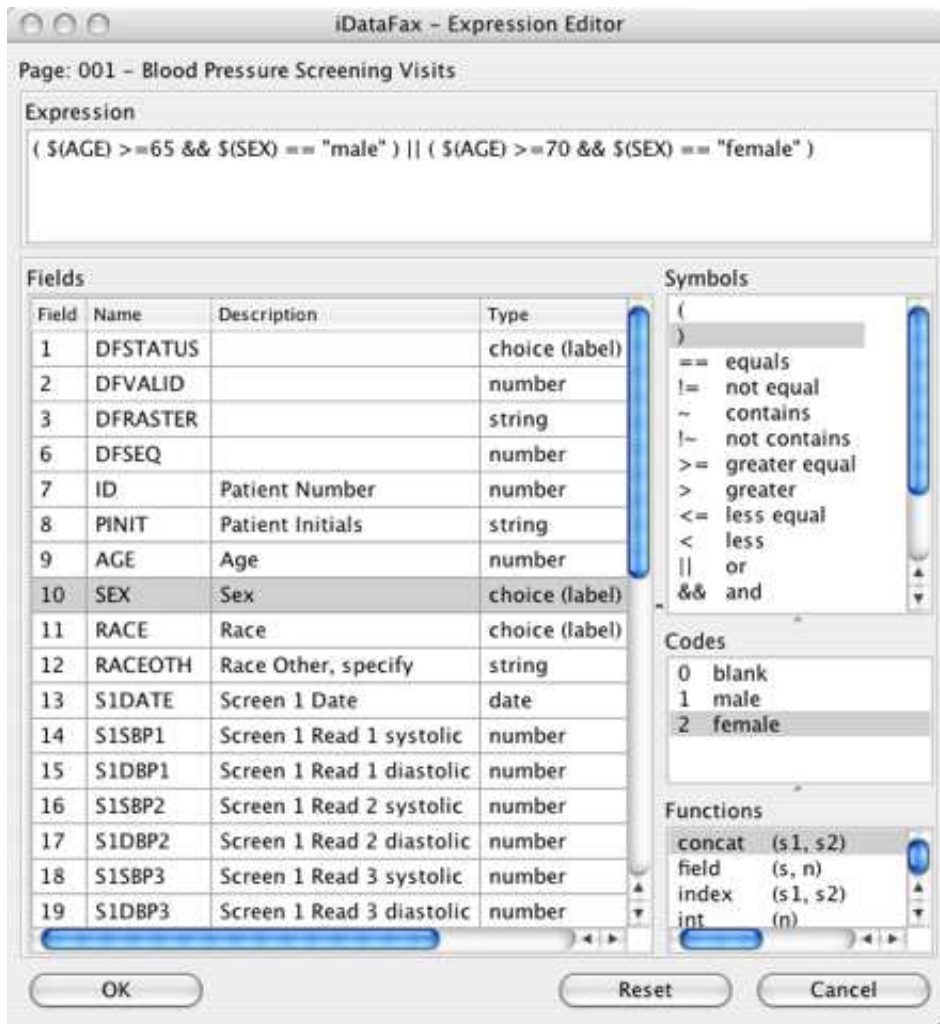
After specifying the search criteria click the Filter button to start the search. A dialog will appear showing the number of records that meet the search criteria and asking for confirmation before filtering the record list to display only these records.

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

To undo a 'Filter' and display all data records for the current plate select All Records from the Show menu. To undo a 'Task' and remove the 'T' icon from all records select All Records from the Search menu.

The Search dialog includes an expression editor which can be used to create simple algebraic statements describing the desired data records. Expressions can be entered directly in the text widget or by clicking on the Fields, Symbols, Codes and Functions in the appropriate order.

Select - Search Expression Editor



This example selects men 65 and older, plus women 70 and older.

Clicking OK will add this expression to the Search dialog.



Numeric Codes and Code Labels

Expressions must be created using code labels, as in the above example for sex, only when labels are being displayed in List View. If the numeric codes are being displayed expressions must test for the codes, not the labels.

Functions:

concat(s1,s2)

Use concat to test the concatenation of 2 strings. e.g. to find records where the concatenation of 2 fields named 'Mtype' and 'Mnum' combined to give the value 'A1234':

```
concat( $(Mtype) , $(Mnum) ) == "A1234"
```

day(n)

Use day to test for a day of the month in a date, e.g. to find records where 'Screen 1 Date' occurred on or after the 15th of any month:

```
day( $(S1DATE) ) >= 15
```

decimal(n)

Use decimal to test the decimal component of a number, e.g. to find records where weight is not a whole number:

```
decimal( $(WEIGHT) ) > 0
```

field(s,n)

Use field to test a specified word in a string, e.g. to find records where the 2nd word in a drug name is "ACID":

```
field( $(DRUGNAME) , 2 ) == "ACID"
```

`index(s1,s2)` Use `index` to find the character position in string `s1` where string `s2` first occurs. e.g. in the following statement local variable 'X' will be set to 3:

```
number X = index("A56GH9","6GH") ;
```

`int(n)` Use `int` to test the integer value (truncated) of a field. e.g. to find a patient's current age in years at visit date 'VDATE' using the patient's birth date stored in field 'BDATE':

```
number age = int((VDATE-BDATE)/365.25) ;
```

`julian("yyyy/mm/dd")` Use `julian` to specify a date, e.g. to find records where 'Screen 1 Date' occurred after Nov.15,2008:

```
$(S1DATE) > julian("2008/11/15")
```

`length(s)` Use `length` to test field length, e.g. to find initials shorter than 3 characters

```
length$(PINIT) < 3
```

`month(n)` Use `month` to test for a month in a date, e.g. to find records created in June of any year:

```
month$(DFCREATE) == 6
```

`substr(s1,n1,n2)` Use `substr` to test a sub-string of a specified field, e.g. to find records where the middle patient initial is "X":

```
substr($(PINIT),2,1) == "X"
```

`time("hh:mm:ss")` Use `time` to specify a time, e.g. to find records created after 6pm:

```
time$(DFCREATE) > time("18:00:00")
```

`today()` Use `today` to test against today's date, e.g. to find records created today:

```
julian$(DFCREATE) == today()
```

`tolower(s)` Use `tolower` to convert a string to lower case before testing it, e.g. to find records containing "inuit" in the Race Other field, ignoring case:

```
tolower$(RACEOTH) == "inuit"
```

`toupper(s)` Use `toupper` to convert a string to upper case before testing it, e.g. to find records containing "INUIT" in the Race Other field, ignoring case:

```
toupper$(RACEOTH) == "INUIT"
```

year(n) Use year to test for a year in a date, e.g. to find records modified in 2008:

```
year($(DFMODIFY)) == 2008
```

If the expression builder does not have the capabilities you require, searching can also be performed using a custom program specified in the last option at the bottom of the Search dialog. Custom programs must be stored in the study ecbin directory and must generate a DataFax retrieval file as output. DataFax includes 2 standard programs, DFmkdrf.ec and DFmkdrf.jnl (described in the Appendix), which can also be used for this purpose.

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

8.7. Saving Defined Views

List Views consisting of specified data fields, field order and record selection criteria can be defined for use by specified users and/or roles using Select-Define Views to bring up the dialog illustrated below.

The steps include the following:

- From the top button on the right select 'New View' then enter a name and description.
- select the plate and data fields, in the desired order. If no fields are specified all fields in plate order will be used.
- select list view options. These will override the users Preference settings for List View when the view is selected.
- specify the roles and logins to identify those who can use the view and those who own and thus can change it.
- specify the record selection criteria. If none are specified all data records for the plate will be retrieved when the task is selected.
- if you want the selected records to form a new task set check the 'new task' option and specify the task mode, level and whether edit checks are to be executed if the user switches to Data View to review and perhaps modify a data record. If the 'new task' option is selected any previous task will be cancelled when the user selects the view.

Select - Define Views

iDataFax - Define Views

View Name: Medical History

Description: review cases with missing or illegal values

Plate: 003 - Medical History

Field List: 7-79

Field Name: generic unique number : name

Coded Field: code label

Date Field: default calandar julian apply imputation rule

User Roles: QC Manager

Logins: dwt

Owner Roles:

Logins: dwt

Created: dwt December 16, 2008 16:13:20

Modified: dwt December 16, 2008 16:13:20

Criteria: match case new task: Validate level 3 enable edit checks

Data Fields

Field#: 9-76

Value: illegal missing blank required

or equals contains

or Query pending outstanding resolved

and external internal

and contains

or Reason pending rejected approved

and contains

Data Records

Status: final incomplete pending lost

Site:

Patient ID:

Assessment:

Level: 1-2

Creation:

Modification:

Expression:

By Program:

Save Done Clear Cancel

**Note**

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

Once views have been defined users can select a view using menu option: Select-By Views which will display a dialog showing the pre-defined view names and descriptions. The current view if any will be cancelled when a new view is selected.

If no records meet the selection criteria for a selected view, a dialog will report that no records were found, the view will be cancelled, and the spreadsheet will return to it's base state showing all data fields and data records. The current view can be cancelled at any time to return to the base state by selecting Cancel View from the Select menu.

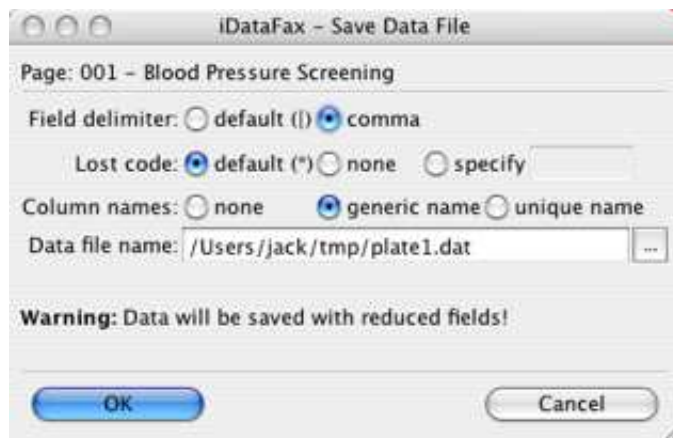
**Select-Cancel View**

Cancelling the current view does not cancel the current task set (if any). The spreadsheet will return to the base state showing all data fields and data records but any task records will remain flagged with the 'T' or 't' icon. Clearing the current task set is a separate operation which can be performed using Select-All Records.

8.8. Exporting Data Records

If you have permission to save data, the records currently displayed in List View can be written to a file on your local disk by selecting File-Save Data File. The print dialog is illustrated below.

File - Save Data File...



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

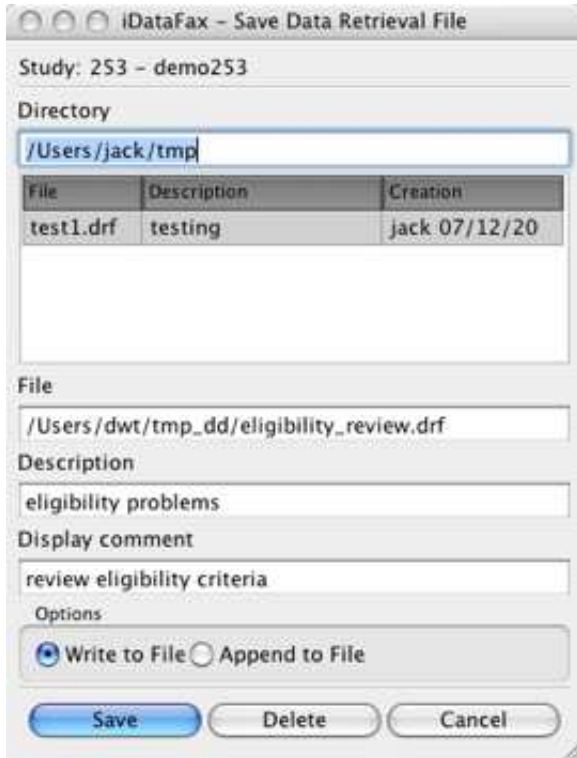
- a field delimiter
- an output value for data fields in lost data records
- column/field names for first output row
- output data file on local PC

Any data fields which have been hidden using Select-Field Selection will not be exported. A warning message: 'Warning: Data will be saved with reduced fields!' will appear at the bottom of the dialog when this is the case.

8.9. Exporting a Data Retrieval File

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

File - Save Data Retrieval File...



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

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

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

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

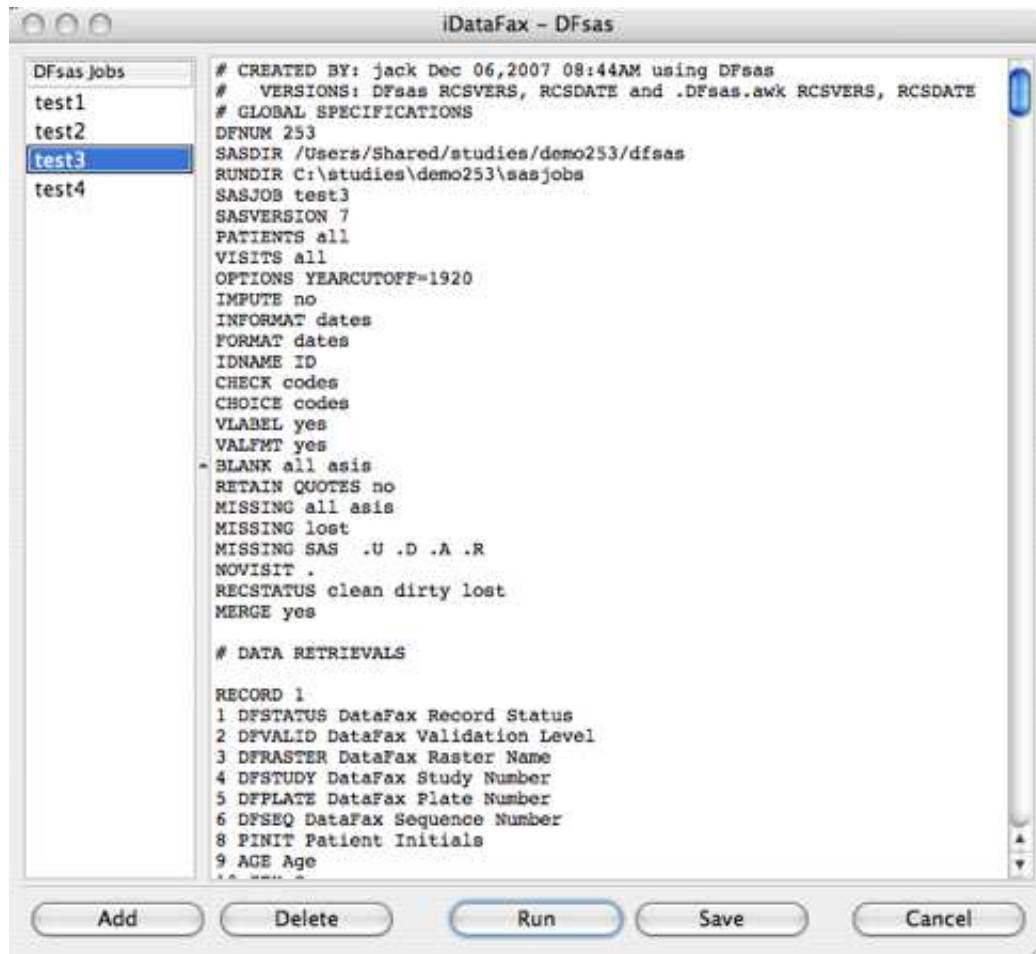
An existing DRF can be selected and deleted using the Delete button.

8.10. Exporting SAS Data Sets

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

For instructions on creating and running DFsas jobs see the DFsas chapter in the DataFax Programmer's Guide.

File - DFsas ...



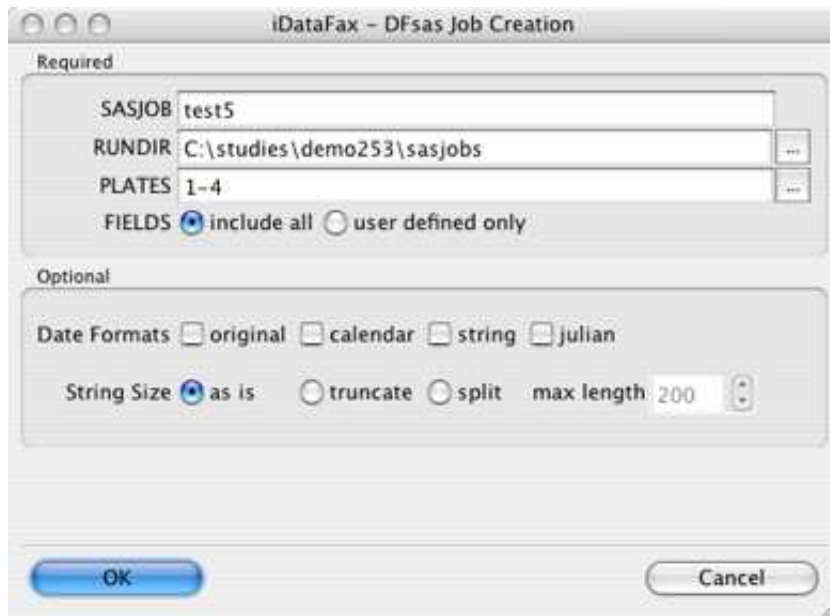
iDataFAX works with DFsas job files located in the study dfsas directory on the DataFAX study server. All existing DFsas job files are listed when the DFsas window is opened and the list is updated if any new jobs are added.

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

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

New DFsas job files can be created by selecting the Add button and using the dialog illustrated below. The new job file will then appear in the text window and can be edited (as described in the DataFAX Programmers Guide) to create the desired DFsas job file.

DFsas - Add



SASJOB: new DFsas job file name

RUNDIR: location on the local PC where SAS job and data files will be stored.

PLATES and FIELDS: a DFsas job file can include some or all data fields on some or all study plates

Date Formats: optional, see below

String Size: long text can be truncated or split into multiple fields

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

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

- original - turns off imputation, outputs the value exactly as stored in the study database, and creates a date informat for SAS.
- calendar - performs imputation as specified in the study setup, converts 2 digit years to 4 digit years, and creates a date informat for SAS.
- string - turns off imputation, outputs the value exactly as stored in the study database, and creates a character informat for SAS.
- julian - performs imputation as specified in the study setup, converts the date to a big number (of days since 4712 BC), and does not create an informat statement as SAS does not need one for numbers.

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

After saving a DFsas job file it can be executed at any time by selecting the Run button. A confirmation dialog appears with one option: Force DFsas to include all specified plates. Select this option if you want to include all of the plates specified in the DFsas job file even if they do not currently contain any data records. If this option is not selected a SAS data statement will only be created for plates with data records.

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

8.11. Importing Data Records

Data from labs and other sources can be imported to a DataFax plate by selecting File-Import Data in List View and following the steps illustrated below. Permission to use this feature must be granted in the user's study role.

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

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

Step 1: Select the Input Data File.

File - Import Data ...

The screenshot shows the 'iDataFax - Input Data File' dialog box. It has several sections:

- Select DataFax plate to import:** A dropdown menu showing '001 - Blood Pressure Screening Visits'.
- Select field mapping file:** An empty text box with a dropdown arrow.
- Select input data file:** A text box containing '/Users/jack/tmp/ScreeningData_150910.dat'.
- Data Preview:** A window showing the first three records of the data file. The first row contains field names: Subject, Initials, Gender, Age, Ethnicity, ScreenDate, SBP1, DBP1, SBP2, DBP2, SBP3, DBP3. The following two rows contain data: '01001,LKJ,1,66,2,15/09/10,142,110,146,110,144,110' and '01002,KAH,1,62,1,15/09/10,138,98,140,100,142,100'.
- Field delimiter:** Radio buttons for 'default (|)', 'comma (,)', and 'Tab'. 'comma (,)' is selected.
- first row contains field names:** A checked checkbox.
- input date format:** A dropdown menu set to 'per study setup'.
- Preview first 5 records:** A checked checkbox.

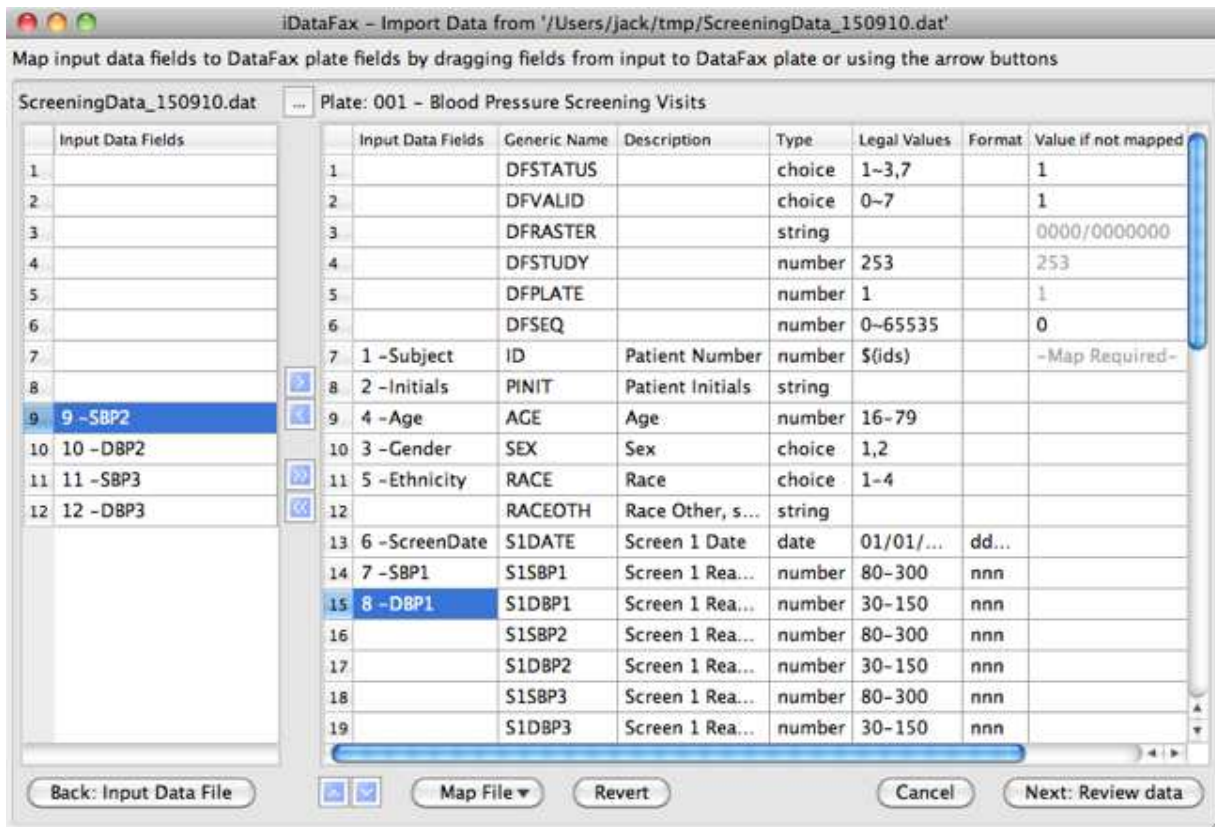
At the bottom, there are 'Cancel' and 'Next: Map data fields' buttons.

1. First select the import destination, i.e. the database plate.
2. If imports from the same source recur, the mapping of input fields to study database fields (described in the next step) can be saved to a mapping file and reused.
3. When the input data file is selected the first 3 records are displayed in a preview window.
4. The input field delimiter must be one of: '|', comma or tab.

5. Having field names in the first input row is useful as an aid to field mapping, but it is not necessary.
6. If the date format used in the input data records differs from the format used in the study plate, enter the input date format to convert dates to the format used in the plate.
7. If the input file is very large, specifying a small number of records to preview allows you to quickly verify that the mapping and data appear correct before loading all of the input data records.
8. To proceed to the next step select the 'Next: Map data fields' button in the lower right corner of the dialog.

Step 2: Map Data Fields.

Next: Map Data Fields



1. To specify the mapping of input fields to database fields simply drag fields from the left panel to the right panel beside the corresponding Generic Name for the field in the study database; or use the buttons to move the current input field in the left panel to the next available slot after the current input field in the right panel. For example, clicking the right-going arrow in the above dialog will move input field '9 -SBP2' to Plate 001 field 16 S1SBP2.
2. The double arrows move all fields to the right panel, or back to the left panel, and can be used when all fields in the input records exactly match fields in the destination plate.
3. Once moved to the right panel, input data fields can be matched with the correct Generic name by dragging them with the mouse or by using the up and down arrow buttons.
4. If the input file contains fields that are not included in the plate they can be omitted. It is not necessary to match and import all fields from the input records.
5. If the plate contains fields that are not included in the input file a value can be specified under 'Value if not mapped', otherwise the field will be blank in all imported data records. If the word 'today' is specified for an un-mapped date field the current server date will be inserted when the data records are

imported.

- The only field that is required in the input file is the patient ID. The visit key field can be specified in the 'Value if not mapped' column, as can any other field that you want to set to the same fixed value for all input records.
- Database records for a specified plate and visit can be deleted by importing a file that contains only the patient ID, and then specifying the relevant visit number and setting status=7 in the 'Value if not mapped' column. No other fixed values are required.
- Plate fields DFRASTER, DFSTUDY and DFPLATE are set automatically and need not be mapped, but if they are then DFRASTER is treated as a key field which must match an existing record when importing replacement records in 'Replace' mode, and must equal '0000/0000000' when importing new records in 'New' mode.
- The time stamps, DFCREATE and DFMODIFY can not be mapped. They are completed by the server when records are imported.
- The Import dialogs have 2 buttons in the lower right and left corners used to move to the next and previous step respectively. During mapping the 'Next' button can be used to review the current mapping of data records, and the 'Back' button can then be used to return to the mapping dialog.
- If other data files with the current mapping will be imported at some point, the mapping can be saved to a file using 'Map File-Save Current Mapping to File'.
- If you forgot to specify a saved mapping file in the previous dialog it can also be selected in the mapping dialog using 'Map File-Read Field Mapping from File'.
- Use the 'Revert' button to undo all current mapping so you can start over, and the 'Cancel' button to abort the whole 'File-Import Data' operation.
- When mapping is complete select the 'Next: Review data' button to proceed to the next step.

Step 3: Review Input Data Records.

Next: Review Data

	DFSTUDY	DFPLATE	DFSEQ	1-Subject ID	2-Initials PINIT	4-Age AGE	3-Gender SEX	5-Ethnicity RACE	RACEOTH	6-ScreenDate S1DATE	7-SBP1 S1SBP1	8-DBP1 S1DBP1	9-SBP2 S1SBP2	10-DBP2 S1DBP2	11-SBP3 S1SBP3	12-DBP3 S1DBP3	S2DATE
1	253	1	0	01001	LKJ	66	1	2		15/09/10	142	110	146	110	144	110	
2	253	1	0	91002	KAH	62	1	1		15/09/10	138	98	140	100	142	100	
3	253	1	0	01003	sha	37	1	1		15/09/10	168	102	164	102	164	104	
4	253	1	0	01004	JHG	59.5	2	1		15/09/10			154	104	156	108	
5	253	1	0	01005	WKD	57	1	1		15/09/10	148	156	146	106	144	104	

- The spreadsheet, illustrated above, displays each data record. Scrolling left and right allows you to verify that all fields have been mapped correctly.
- The 'Get All' button at the bottom of the dialog indicates that we are looking at the number of records that were specified for 'Preview'. Selecting 'Get All' loads the remaining input records as illustrated in the example below.
- Problem fields are identified by color using: purple for invalid values which prevent the record from being imported, yellow for values which will be auto-corrected on import, and red for illegal values, which will be imported as is.
- Selecting the 'AutoCorrect' check box reveals how the yellow fields will be corrected. As illustrated in the example below the Initials 'sha' change to 'SHA' because this field was defined with upper case mapping, and Age 59.5 is truncated to 59 because this field was defined as a number with no decimal places.
- Corrections can be made by editing the values in the spreadsheet. As illustrated in the example below, Subject ID 91002 was corrected to 01002, and for Subject ID 1005 S1DBP1 was corrected from 156 to 106.

- The data records can be filtered using the check boxes at the top of the dialog to display any combination of records with invalid, illegal and autocorrect values, or records with no problems at all.
- Auto-Corrections:

Auto-corrections that change the input value include:

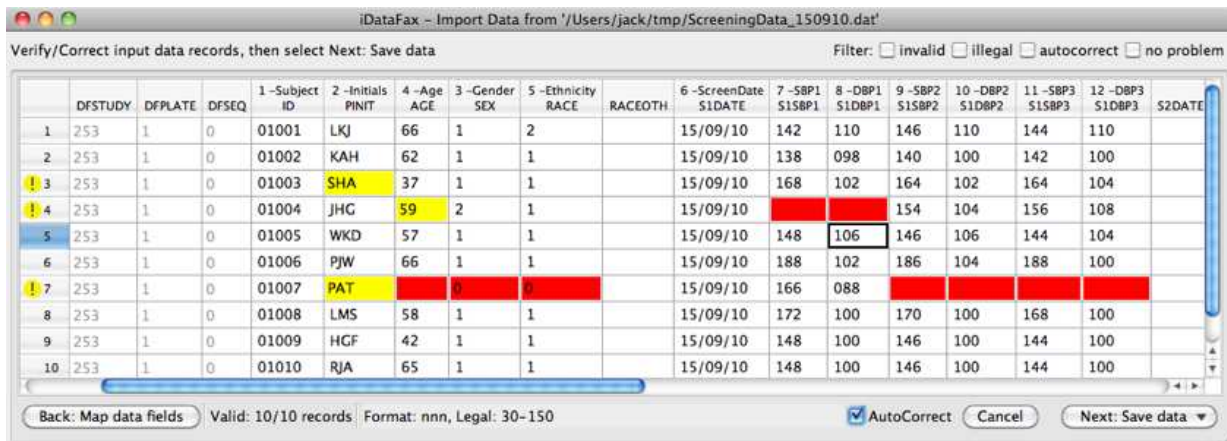
- Strings longer than the field store length are truncated
- Numbers are truncated to the number of decimal places in the field format
- Numbers greater than the field store length are imported as blank fields
- Undefined codes in choice and check are imported as blank fields
- Invalid dates are imported as blank fields

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

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

Step 4: Get All Data Records.

Get All



- The 'Next: Save data' button can be used to either import the records to the study database or save them to a file on disk.
- Only valid records displayed in the spreadsheet will be saved, so make sure to select 'Get All' and check your 'Filter' options before proceeding to the next step.

Step 5: Save Data Records.

Next: Save Data

iDataFAX - Import Records to DataFAX Database

10 valid records

Mode

New - add data records to the database

Replace - replace existing data records

Merge - add data records to the database, or replace existing data records

Queries

Resolve missing value queries when a legal value is imported

Resolve illegal value queries when a legal value is imported

Create missing value query when blank is imported to a required/essential field

Create illegal value query when an illegal value is imported

Add Reasons to database fields that are changed by imported replacement records

Add Pending reasons

Add Approved reasons for records with Approve Reason permission, otherwise add Pending reasons

Task Set

Create a new task set containing all imported records

Create a new task set containing imported records with illegal/missing values

Mode:

Sign Off Level: Enable edit checks

Back: Review data Next: Import data

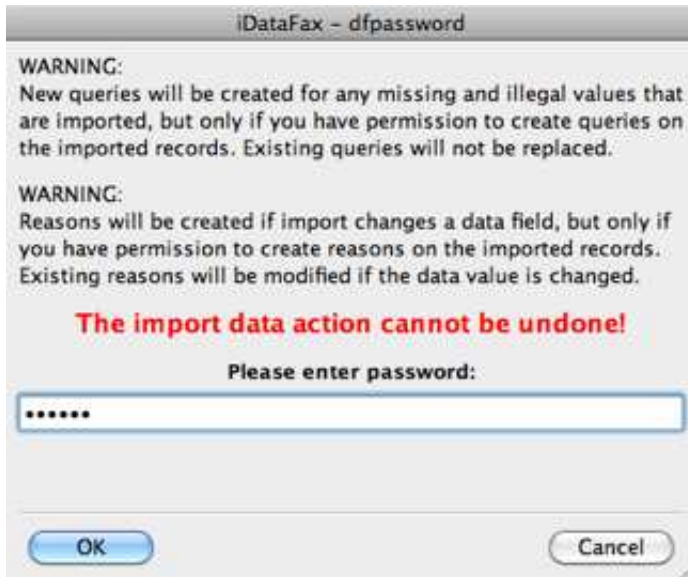
1. If from the 'Next: Save data' button you select 'Save Records to Local Data File' you will simply see a file selection dialog, but if you select 'Save Records to DataFAX Database' you will be presented with the dialog illustrated above.
2. Select Mode = 'New' if all input records have keys (ID,visit,plate) that do not already exist in the study database. When using this mode only new records will be imported; any replacement records will be rejected.
3. Select Mode = 'Replace' if all input records have keys (ID,visit,plate) that already exist in the study database. When using this mode only replacement records will be imported; any new records will be rejected.
4. Select Mode = 'Merge' if the input file includes both new and replacement records.
5. Among the Queries options we recommend that you resolve missing and illegal value queries if a legal value is imported, otherwise the queries will not correspond to the corrected values and will likely confuse users. None of the other query problem types can be logically auto-corrected in this way and thus remain unchanged.
6. Queries can also be created automatically during import to flag missing and illegal values. If these options are selected existing queries will not be modified or replaced, new queries will only be created for fields that do not already have a query.
7. Selecting the 'Add Reasons' option adds the reason 'Set by iDataFAX Import' to database fields that are changed when a replacement record is imported. Reason status can be set to 'Pending' review, or 'Approved' requiring no review, but reasons can only be approved if the user has permission to approve reasons on the records being imported. If this is not the case reasons are created with the 'Pending' status. Reasons that are created during import replace any existing reasons on the fields

that are changed. The previous reasons are then only available in the audit trail report or by selecting 'Show History of all Changes' in **iDataFAX**.

8. Use the 'Task Set' option to review the imported data records when import is complete. The task set can contain all imported records or only those missing and illegal values, which might be useful if you want to review any queries generated during import. As when creating any task set, you also need to specify the: mode, sign off level and edit check status, to be used on records in the task set.
9. When these options have been completed select 'Next: import data' to proceed to the final step illustrated in the dialog below.

Step 6: Confirm Import Data.

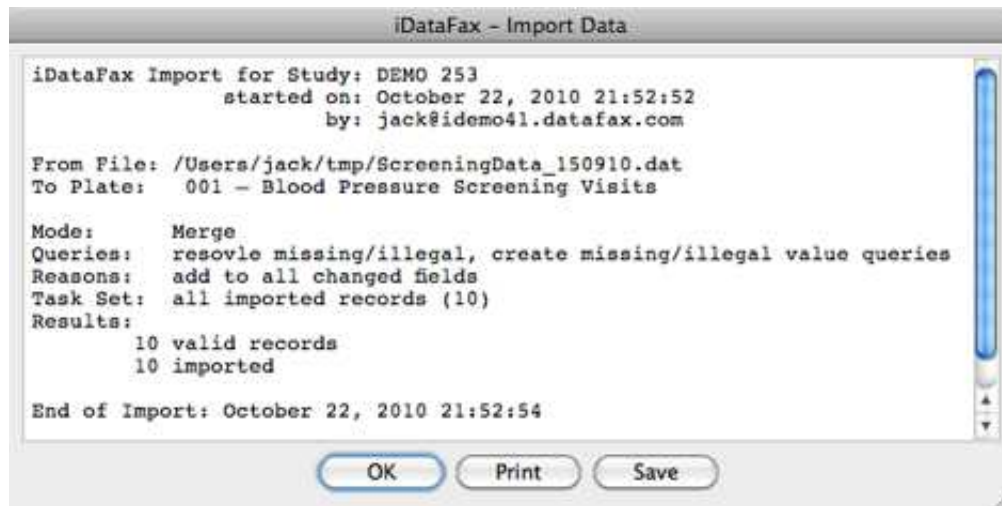
Next: Import data



1. If you selected the options to create queries and reasons in the previous dialog you will see the warning messages illustrated above.
2. To start data import enter your password and select 'OK', or select 'Cancel' to return to the previous dialog.

Step 7: Review Results.

Next: Map Data Fields



1. The dialog illustrated above appears when the import is complete, with a summary of the import specifications and results.
2. If any records are rejected, e.g. because you selected Mode:New, but some input records already existed in the study database, they will be displayed in this dialog along with the reason they were rejected. Also, a 'Save Rejected Records' button will appear so that these records can be saved to disc. This allows you to deal with the problem(s) that blocked import and try again.
3. We recommend keeping a record of all data imports by printing or saving this report. While the audit trail will show any new records and data changes made during import by: date, time and the user who performed the import, it does not distinguish between data entered and saved in Data View and records that were imported in List View.

Input data records may be rejected for the following reasons:

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

8.12. Metadata - Queries, Reasons, QC Reports and Lost Records

In addition to displaying patient data records List View also displays queries, reasons, returned QC reports and records that have classified as 'lost'. Users who have permission to see a data record automatically have permission to see queries and reasons attached to fields on that record. Permissions for QC reports must be granted explicitly through plate 501, otherwise QC reports will not appear in List View. Lost data records follow the same permissions as regular data records.

Changes can only be made in Data View. Double clicking anywhere on a metadata record in List View switches the user to Data View with the focus on the field that was double clicked. Selecting the 'Return to List View' button in Data View will return the user to the field that was double clicked in List View.

Queries can be searched using Select-Search to invoke the dialog illustrated below. This dialog shows the number of queries that meet all of the current search criteria. After entering new criteria click Update to update the counts.

Search Queries



In this example 47 queries match all of the specified criteria.

Use 'Save' or 'Print' to output the criteria and counts shown in this dialog.

Click 'Filter' to select these 47 queries and remove all others from the current list view.

Click 'New Task' to put the data records with these queries into a new task set.

After clicking the Filter button to reduce the list to just those queries that match the search criteria, new criteria can be specified to narrow the search further within the previously filtered set.

Records matching new search criteria can be added to a current task list by clicking the Add to Task button.

If you fax or email Quality Control (QC) reports to the sites they may respond by writing directly on a printed copy of a report and faxing it back to the DataFAX system. Returned QC reports are not patient CRFs and thus are not displayed in a patient binder. They can however be processed in Fax View, just like data records, and saved in the study database with key fields: ID equal to the QC report number (composed of the site number and QC report creation date), and Sequence equal to the QC report page number. Any QC reports that have been saved in this way can be reviewed in List View.

If you have permission to modify returned QC reports you will be able to correct any errors that might have been made when the key fields were entered. To make corrections first use 'Select-Change Mode & Level' to set mode to anything except 'View', and then use 'Page-Change Keys' to bring up the Change Keys dialog.

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

Work flow tasks can also be performed on QC reports in List View. For example, new QC reports will typically be saved at level 1 when they arrive in Fax View. Someone may then have the task of reviewing them and moving them to level 2 to indicate that they have been reviewed. To perform this task use 'Select-Change Mode & Level' to set mode to Validate and Level to 2. Next use 'Select-Search' to find the QC report pages that are currently at level 1. Then after reviewing each page, save it by selecting Final or Incomplete. This will move the page to level 2. You can use the search dialog again at any time to find the pages that currently have incomplete status.

8.13. List View Menus

This section describes the List view options available under the Select and Show menus which appear at the top of the screen. The options available under the remaining menus have already been described for the Data view.

8.13.1. The Select Menu

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

- All Records ... - cancel current task set (if any) and show all data records for the CRF page currently selected in the left panel of the List view dialog. When cancelling a task set a new mode and sign-off level can be specified in a pop-up dialog.
- Field Selection ... - select and arrange the data fields page to be displayed from the current page.
- Search ... - specify criteria used to find data records, reduce the rows in the List view table to those meeting the specified criteria, and/or to create a new task set.
- By View ... - select data records (rows) and data fields (columns) using a pre-defined view.
- Cancel View - cancel previous By View selection to display all data records and data fields for the current page.
- Refresh - update all data records for the current page from the study server to get new records that may have been added or changes that may have been saved since the view was opened.

8.13.2. The Show Menu

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

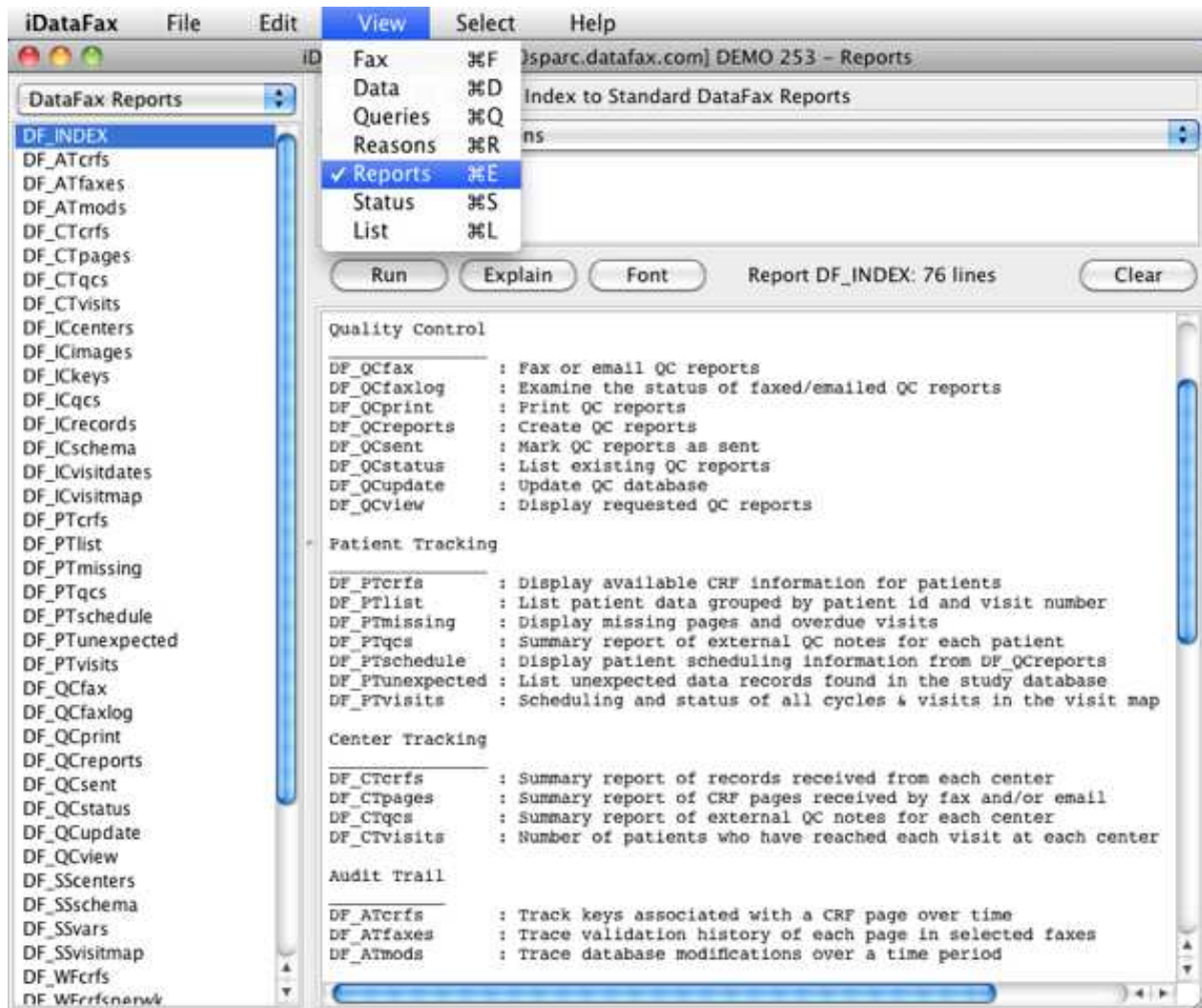
- All Pages - show all page types defined for the study
- Task Pages - show only those page types included in the current task set
- All Records - show all data records for the currently selected page type
- Task Records - show only those data records included in the current task set

Chapter 9. The Reports View

9.1. Introduction

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

Figure 9.1. View - Reports



9.2. Report Types

The button above the list of reports has 3 options.

1. **DataFax Reports:** Selecting this option will list all of the standard DataFax reports for which you have permission. The standard reports are designed to address common trial management needs, like summarizing data management status for individual patients and clinical centers.
2. **Study Reports:** Selecting this option will list the study specific reports, designed by programming staff at the trial coordinating center, to address needs not covered by any of the standard DataFax reports.
3. **History:** Each report you run is added to the History list. You can review the output from any report by opening this list and selecting the report. If you run a large number of reports or the output from some of your reports is very long you may exhaust the memory cache used to save the output from each report. If this occurs you will not see any output on selecting some of the older reports from the history list. But you can re-run reports from within the history list by selecting Run. The report will then run, with the same options used the first time, unless you change them, and will itself be added to the end of the history list.

9.3. Explain - Report Documentation

All DataFax reports and most Study reports will include documentation that can be accessed by selecting the report name and then selecting the Explain button. The documentation generally includes a description of any options that may be specified before the report is Run and an explanation of the report output.

9.4. Report Options and Database Permissions

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

Selecting the Options widget displays the entire options list. Selecting an option from the list copies it to the Specify window with the part you need to change highlighted. For example, the DF_PTcrfs option used to limit the CRF history to patient visits occurring since a specified date is: -t yy/mm/dd. When this option is selected it is copied to the Specify window with yy/mm/dd highlighted. Changing this to 07/05/15 yields the option -t 07/05/15 which limits the output to patient visits which occurred after May 1, 2007.

9.5. Running Reports

Selecting the Run button runs the report with the options currently listed in the Options Specify window and displays the results in the large scrolling window below the Run button. The output from each new report replaces the output from the previous report. However, by switching to the History list you can review the output from all reports you have run since login. The run history is not saved between login sessions.

The current output in the report window can be printed or saved, in PDF, HTML or text format, by selecting any of these options from the File menu.

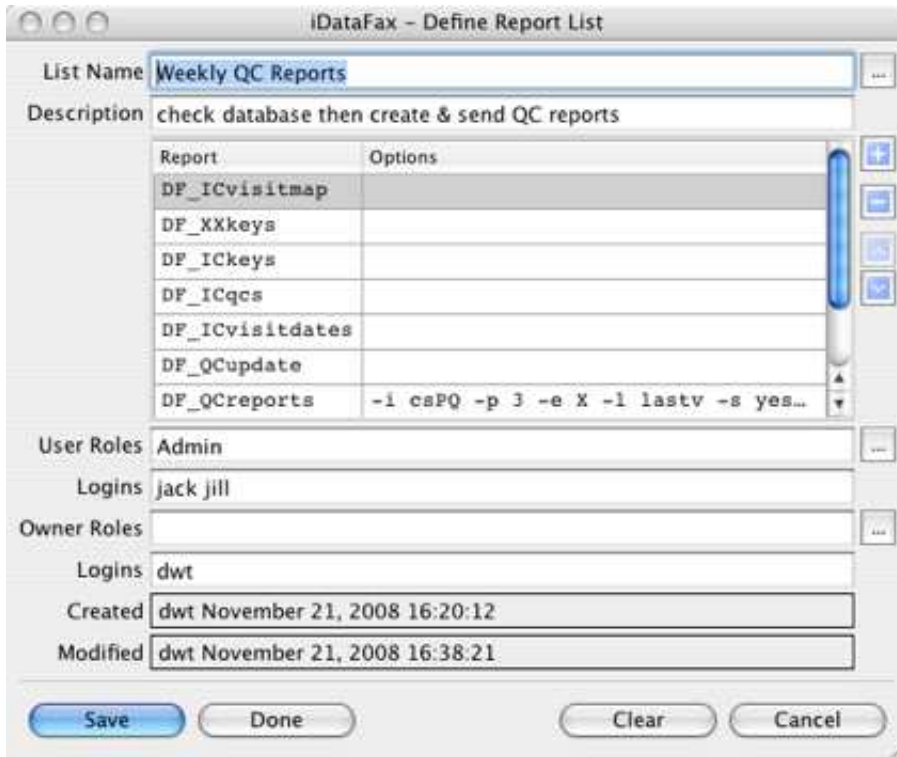
9.6. Saving Report Lists

A list of commonly executed reports can be saved for later execution by specified users and/or users with specified roles. You can also specify the user and roles that are permitted to own and thus modify each report list you define. The permissions granted at this level do not over-ride the permissions defined in user roles. If a user lacks permission for any report in a report list the entire list will be unavailable in iDatafax.

A report list is defined using Select-Define Report List and is subsequently accessed using Select-Report List. Reports and report options may be added to a report list manually in the dialog shown below, or the current history list can be used as a starting point and then modified. Begin by selecting the button at the right end of the 'List Name' field at the top of the dialog. Then select 'New Report List' to define the list manually or 'New Report List from History' to begin with the reports contained in the current History list.

The following example shows a list of reports used to create and send QC reports to the study sites each week.

Select - Define Report List



Give each report list a name and one line description.

Remember to include the desired options for each report.

Users must have permission to run each report in the list.

Owners will be able to modify the report list.

To access a previously defined report list use Select-Report List to invoke the dialog illustrated below and select the desired report list.

Select - Report List

This example has 2 report lists.

The first one has been selected.

The 3 reports it contains are displayed with their options.

'all reports' has been selected thus the reports will be run in order when 'OK' is selected. The output will be added to the current History list.

The individual reports and report options are displayed for the selected list.

All reports can be executed in the order they appear in the list by selecting Run 'all reports' and then clicking 'OK'. The output from each report will be added to the current History list. When the last report finishes the 'History' section of Report View will open so that the output from each report can be reviewed.

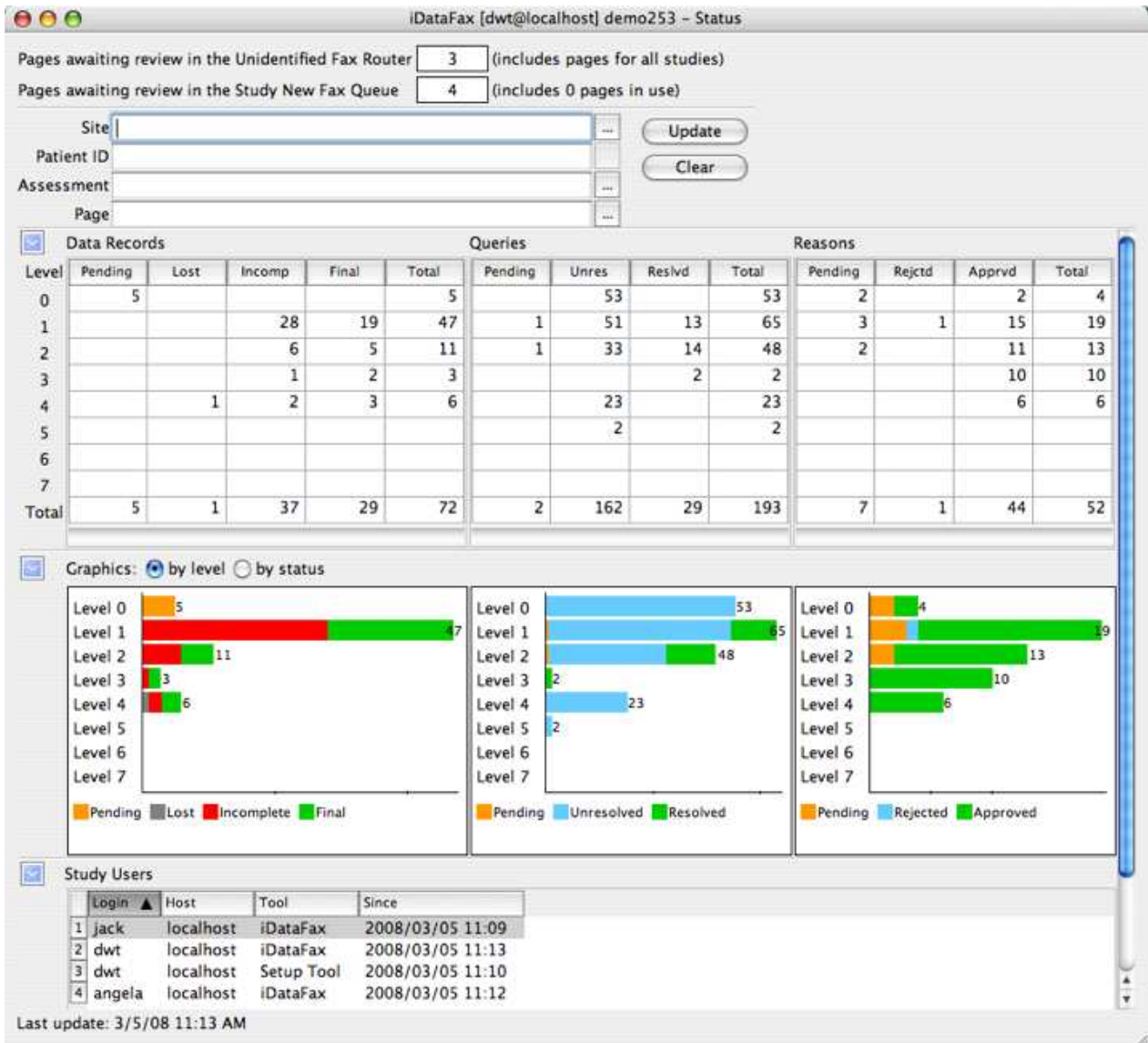
Alternatively, reports can be executed one at a time by selecting the 'selected report' option, selecting a report from the list, and then clicking 'OK'.

Chapter 10. The Status View

10.1. Introduction

The Status View provides a quick overview of the status of the study database and shows a list of users who are currently working on the study. It can also be used to quickly assemble a set of records to perform some task by double clicking on any cell in any of the 3 tables.

Figure 10.1. View - Status



10.2. Level & Status

The Status View displays the number of data records, queries and reasons that are currently stored in the study database categorized by the work flow level and status with which each record was most recently saved. Status labels have been shortened as needed to fit within the tables, but the full label can be seen by hovering over the table labels or selecting the Graphics by status option. Work flow level 0 identifies new data records that were saved with pending status, and queries for overdue visits. Level 1 is typically used for new data entry; leaving higher levels for various central office checks and reviews.

10.3. Filtering The Status Report

When the Status View is first invoked it displays the status of the entire study database. The results displayed in the tables and graphs can be filtered by study Site, Patient ID, study Assessment (or visit) and CRF Page. In each case the legal entry is a number, e.g. site number not site name. The button to the right of each entry widget can be used to display and select valid entries for each specification, except patient ID. A list of values and ranges can be entered, e.g. Site: 1-9,21,30-44,81,82. Click the Update button to apply the current filter and the Clear button to remove all filter specifications. After clicking Update, any filter specifications will remain in effect for the duration of your login session. To reproduce status for the entire study database select the Clear button and then the Update button.

10.4. Links

You can jump to the records displayed in any cell of the table, including row and column totals, by double clicking the cell. Double clicking a cell in the Data table will create a Task set containing the records in that cell and open them in Data View. Double clicking cells in the Queries table opens the task set in Queries View and double clicking cells in the Reasons table opens the task set in Reasons View. Of course this only works if the user has permission to use these views.

10.5. User Permissions

The information displayed in Status View depends on user permissions. The tables and graphs include only records the user has permission to see, and the counts shown for records available in the Unidentified Fax Router and the New Fax Queue will only be displayed if the user has permission to use Fax View and the Unidentified Fax Router.

10.6. New Fax Queue

The top of the screen Status View displays the number of study CRF pages that have arrived by fax and are waiting to be reviewed and entered into the study database. These records are not counted in the Data table. This count is only visible to users who have permission to use Fax View to review and enter these pages. Double clicking on the count will open Fax View for such users.

10.7. Unidentified Fax Router

At the top of the screen Status View also displays the number of CRF pages that have arrived by fax but could not be routed to any of the current DataFax databases because the study number could not be identified. These pages need to be reviewed and routed to the appropriate study if they are in fact study CRFs. This count is only visible to users who have permission to use the Unidentified Fax Router to review and dispatch these pages. Double clicking on the count will open the Router for such users.

10.8. Returned QC Reports (plate 501)

Status View does not include any QC report pages that have been faxed back from the clinical sites and stored in the study database as plate 501, nor does it include any queries or reasons that may have been added to these records. Returned QC reports and any associated metadata can be reviewed in List View.

Chapter 11. Unidentified Fax Router

11.1. Introduction

When DataFax receives pages which it cannot recognize, it stores them in a special folder where they can be reviewed using the **iDataFax** router.

Pages need to be routed only if DataFax is unable to find or read the DataFax bar code at the top of the page. This occurs when there is no bar code (e.g. memos, letters, cover pages), or when the bar code is obscured (e.g. by fax noise, a coffee stain, something printed over it).

Without a readable bar code DataFax can not identify the study. Thus all unidentified pages are stored in the same unidentified page folder. If you are running several studies, the individuals who review and identify pages using the router must be sufficiently familiar with all studies to correctly route each page.

Study CRFs are not difficult to identify correctly unless the bar code is missing altogether. In such cases the contents and design of the CRF may be enough to correctly identify it. If not, selecting Context from the Page menu can be used to determine where the page came from.

Also, remember that DataFax creates missing plate and over due visit queries for required CRFs and visits that have not arrived (as specified in the study visit map). Thus queries may be generated for pages that have been transmitted by the sites but are currently stuck in the router unless such pages are identified before the DF_QCupdate program is scheduled to run.

While this chapter refers to the processing of unidentified pages received by fax, the same procedures apply to unidentified pages received by email as .pdf or .tif attachments, or submitted using DFInotify.rpc, after being scanned.

11.2. Router Functions

The router is used to:

1. Review all unidentified pages.
2. Get context (determine when the fax arrived and where it came from).
3. Delete pages that are not needed (e.g. fax cover sheets, blank pages).
4. Print non-CRF pages or save them to a PDF file.
5. Fix any fax transmission problems (e.g. flip, rotate, truncate, cut).
6. Identify CRFs and other patient documents and send them to the correct study database.

11.3. Restrictions

Three factors determine what a user can do in the router:

Router Permission. Users with router permission can start the router and view, print, delete and check the context of all unidentified pages that arrive on the DataFax server. They can also identify and send pages to any study on the server, even if they have no other study permissions, with the following qualifications.

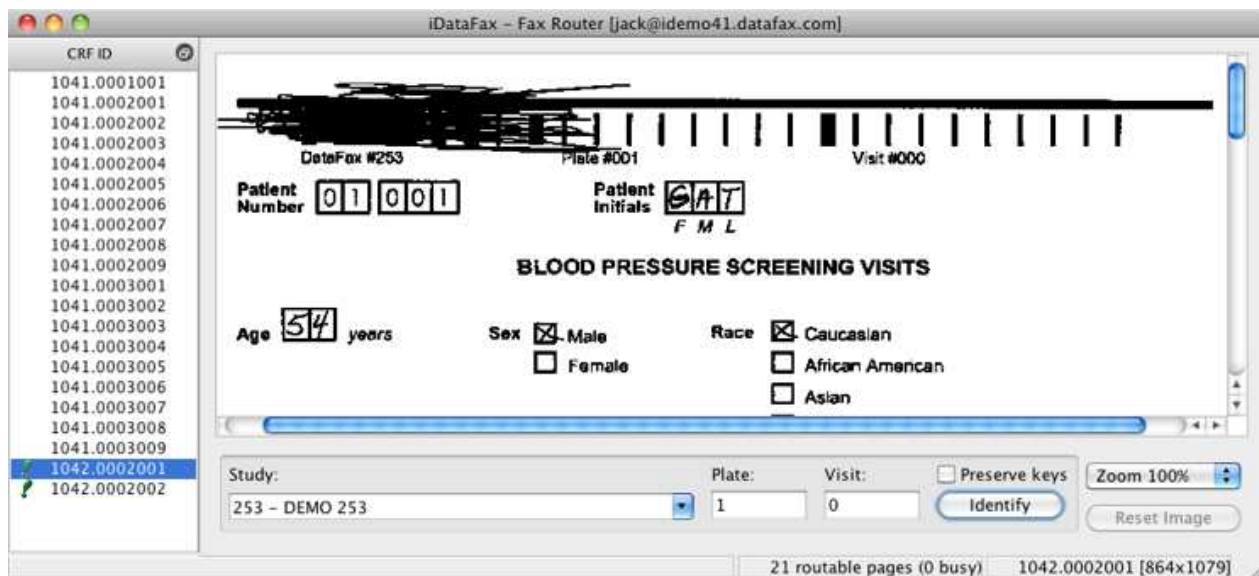
Study Status. DataFax and study administrators can place temporary or permanent restrictions on a study by changing it's status to: disabled, read-only, restricted (for administrators only), or both restricted and read-only. Pages cannot be sent to studies that are disabled or in read-write mode.

DataFax and Study Administrators. Only DataFax and study administrators can send pages to a restricted study. If a study is also in read-only mode, or is disabled, not even administrators can send pages to the study.

11.4. Starting The Router

Start the router by selecting the Fax Router button located on the study selection dialog that appears right after the iDataFax login dialog. This button only appears if you have permission to use the router.

Figure 11.1. The main router window.



Each page, shown in the page list on the left side of the screen, is identified by an image name in format yyww.ffffppp, where yy is the year, ww is the week, ffff is the fax transmission ID, and ppp is the page number within the transmission. The router can be used simultaneously by multiple users. Pages are locked and released as the user traverses the page list. When a page is selected it and all other pages in the same fax transmission are locked preventing other users from processing the same pages.

Small icons show the current status of each page in the page list. Exclamation mark icons identify pages that are locked by the current user; lock icons identify pages currently locked by other users; and red X icons identifies pages that have been processed (routed to a study, deleted, or saved). The user's login name and the DataFax server name are shown in the title bar, and a similar message bar at the bottom of the screen shows the number of pages to be routed, the number of pages locked by other users (busy), and the current image name and size in pixels (width x height).

Router work flow typically proceeds in 3 steps: (1) select a page, (2) perform image processing (e.g. rotation, flip, etc.), and (3) identify the study it belongs to using the widgets at the bottom of the screen, or print or discard it using the menus at the top of the screen.

Pages without barcodes may also be identified, provided the user is able to determine the study, plate and visit numbers using other features. As an aid to identification the image can be resized from 50-200% using the Zoom option. This has no effect on the size of the image stored in the study database.

If most pages have similar keys the 'Preserve keys' check box can be used to prevent the key fields (study, plate and visit) from being cleared when each new page is selected.

If a set of pages all have the same keys and do not require image processing, they can be identified together in one step by making multiple selections from the page list before clicking the identify button.

The router sends all identified pages, whether barcoded or not, to the new record queue where they are processed in Fax View, along with pages that were identified automatically from their bar codes.

The rest of this chapter describes the options available under each of the menus at the top of the screen.

11.5. The File Menu

11.5.1. Update Records

Select Update Records from the File menu to update the page list with any unidentified pages that may have arrived since the current session began.

11.5.2. New Study

Select New Study from the File menu to open the study selection dialog and select a study, while keeping the router window active.

11.5.3. Close Router

Select Close Router from the File menu to close the router window and return to the **iDataFax** login dialog.

11.5.4. Exit

Select Exit from the File menu to exit the router and **iDataFax**.

11.6. The Page Menu

This menu contains a number of functions which allow you to manipulate pages (rotate, shift, flip, cut, truncate, and reset) to clean them up before sending them to the study database.

It also contains functions for turning to the next or previous page, printing pages and determining where each page came from (context).

11.6.1. Rotate

Select Rotate from the Page menu to correct page skew. This is needed if the page signature line at the top of a study CRF is not perfectly horizontal. Page skew usually results from failure to adjust the page guides snugly against the sides of the CRF pages when they are being scanned by the fax machine.

Instructions for this operation appear in the status line at the bottom of the router window. Click the left mouse button on the top left end of the horizontal signature line and then click again on the top right end of this line (or click the right mouse button to cancel this operation). When the operation is complete, the screen will update to show the realigned image. You can undo a rotation by selecting Reset from the Page menu.

11.6.2. Shift

Use Shift when the page does not need to be rotated. Shift is used to register the upper-left corner of the page signature line found at the top of all DataFax CRFs. The upper left corner of this line is used as the CRF reference point for DataFax ICR and thus must be registered before the page is identified and routed to the study database. If you fail to do this the ICR software will look for data in the wrong places on the CRF page and will thus fail to find data fields and will leave them blank.

To shift a page click the left mouse button on the top edge of the horizontal signature line (or click the right mouse button to cancel this operation). After clicking the left mouse button once, the screen will update with the shifted image.

If you make a mistake select Reset to undo the shift and try again.

11.6.3. Flip

Selecting Flip from the Page menu turns the page upside down. Selecting it a second time will return the page to its original position.

11.6.4. Cut

Occasionally you will receive a faxed page which is really 2 pages (or more) joined together. This will be evident by a page length count far greater than 1050 pixels, and also by the vertical scroll bar which will be reduced to half the screen length or less, depending on the number of pages joined together. In such cases you need to cut the one long page into individual pages at the appropriate page boundaries.

Selecting Cut from the Page menu brings up a horizontal line. Move this line to the desired cut position and then click the left mouse button to register it, or the click the right mouse button to cancel.

After the cut point is registered a second dialog box will appear, asking you to confirm this action. Click OK to cut the page or Cancel to abort. A page cut operation can not be reversed thus make sure you want to proceed before confirming this action.

Cutting a page creates 2 pages from the original one. You will see this confirmed by an increase of 1 in the number of faxes reported in the top border of the router window. The top half of the cut page will become the current page displayed in the router window and the bottom half will become the next page.

In very rare cases you might see the following error message: `error Unable to add new image.` This indicates that the image can not be found in `$DATAFAX_DIR/work/fax_log.idx` (the faxlog index file). If you encounter this message contact you DataFax system administrator for assistance. If the faxlog is complete and the only problem is the index file, it can be regenerated, but if the faxlog is not complete the audit trail will need to be searched to locate the relevant fax, discover the last page number, and create a new fax log entry, before reindexing the faxlog.



Warning

The Cut action can not be undone.

11.6.5. Truncate Length

The size of the page (width x length, in pixels) is shown in square brackets at the bottom of the screen. After a CRF has been shifted to the top of the page signature line it should not be longer than 10.5 inches. The resolution of each page is 100 pixels per inch. Thus a length greater than 1050 pixels indicates that the page is too long. In such cases you should examine the bottom of the page to see if it just contains fax noise. If it does, select Truncate Length from the Page menu to remove the excess length.

If you make a mistake, select Reset from the Page menu to undo the > Truncate Length operation.

11.6.6. Trim Width

Fax machines that can accommodate pages wider than 8.5 inches require their paper guides set to 8.5 inches for proper scanning of letter-size pages. If the guides are set too wide, the paper can tilt or shift, resulting in skewed or abnormally wide images. When pages like this are received, they generally appear in the router because they are wider than the 864 pixel maximum. To route a wide page, you can trim the width of a page by selecting Trim Width from the Page menu. Two dashed vertical lines appear over the document spaced 864 pixels apart. Using the mouse, position the lines over the area of the page you want to preserve. Click the left mouse button to discard the page area which lies outside these two lines, or click the right mouse button to cancel the operation. If you make a mistake, select > Reset from the Page menu to undo the > Trim Width operation.

11.6.7. Rotate 90° CW/CCW

You can rotate a page 90° clockwise by selecting Rotate 90° CW, or counter-clockwise by selecting Rotate 90° CCW, from the Page menu. Each time you select this menu option, the current page is rotated 90° in the specified direction. This is useful when a sender faxes a page to you sideways and you want to put it into a portrait orientation. If you make a mistake, select > Reset from the Page menu to undo all operations on the page, or rotate the page in the opposite direction to return it to its previous orientation.

11.6.8. Rotate 90° CW/CCW and scale

It is possible to process landscape pages by rotating them into portrait orientation and scaling them to fit the width of a portrait page. This is achieved using Rotate 90° CW and scale or Rotate 90° CCW and scale. Select the appropriate menu item to apply the needed rotation. The page will be rotated and then scaled automatically to fit the width of a portrait US letter page.

11.6.9. Print

To print one or more pages select the page or pages you want to print in the page list, then select Print from the Page menu to get the standard Print dialog box for your PC.

11.6.10. Export as PDF

To export one or more pages in a PDF file select the page or pages you want to print in the page list, then select Export as PDF from the Page menu to get the standard file save dialog, and specify the file name you wish to use.

11.6.11. Previous

This function moves you to the previous page in the router window.

11.6.12. Next

This function moves you to the next page in the router window.

11.6.13. Context

This function can help you determine where an unidentified page came from. It provides the page number within the fax, the date and time on which the fax was received, and the G3 sender identification header from the fax - which is usually the sender's fax number.

Figure 11.2. The Context window.



If the `sender id` is unknown, it will be represented by "" following the sender id label. If DataFax can determine the fax number or email address of the sender's fax machine, as in the above example, it will appear following the sender id label.

11.6.14. Reset

Selecting this function, or the 'Reset Image' button in the bottom right corner of the screen, will undo all Rotate, Scale, Shift, Flip, Trim and Truncate manipulations that have been made to the current page; the only exception is Cut, which can not be undone. Reset is performed automatically if you select a different page before identifying the current one to send it to the desired study database. Once a page has been identified it is gone and any page manipulations become permanent.

11.7. The Action Menu

This menu contains all of the functions which dispatch and remove pages from the DataFax `identify` folder where all unidentified pages are stored. All actions are immediate. Once committed they can not be undone.

11.7.1. Rotate/Shift/Identify

Most CRF pages can be cleaned up, identified and routed to the appropriate study database in a single step by selecting Rotate/Shift/Identify from the Action menu. Follow the directions at the bottom of the router window to identify the CRF page signature line. The page will then be deskewed and shifted and another attempt will be made to read the bar code. When this has been done enter or correct the keys (Study, Plate and Visit) as needed and click the Identify button.

If the plate is defined as having the visit number in the bar code it must be entered before clicking Identify; an error message will appear if you fail to do this. Alternatively, when the visit number is the first data field on the plate the Visit key should be left blank, but will be silently ignored if you enter one.

A Right-Click will abort the Rotate/Shift/Identify action. Once the Identify button is selected, the action is committed and cannot be undone. The page will then be sent for ICR processing and routed to the designated study database. There will be a brief pause while this is being done. Then the page will disappear, and the next unidentified page will be displayed (if there is one).

11.7.2. Move

Select Move from the Action menu to move a page to a specified file name somewhere on your local PC. This will display your standard file system navigation dialog used for selecting folders and files. Moved files are removed from the DataFax server and stored in PNG format on the user's local computer.

11.7.3. Discard

To discard an image, select the image to discard in the page list, then select Discard. A confirmation dialog will then appear, and if you click 'Yes' to discard the image it will be permanently deleted from the study server. This can not be undone.

You can discard multiple pages by selecting more than one page from the page list before selecting Discard.

Chapter 12. User Preferences

File - Preferences

iDataFax – Preferences

User: jack
Study: DEMO 253

Data Window:

expand all assessments when a patient binder is opened
 display first page when an assessment is opened
 advance to next field after current field is completed
 open first task record when task set is built
 warn before opening next patient when traversing task records
 retain scroll position when traversing task records

Image Window:

auto open/close as image is available/unavailable
Display method:
 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
 split screen: image top, data bottom
 sticky toggle: retain data or image view across records

Record List:

Show assessment: number : label number label
Show page: number : label number label
Show site: number – label number label
Record navigation: patient binder record list

Query Defaults:

Use: external internal
Type: clarification correction

List View:

show field name: generic unique number : name
show coded field: code label
show date field: default calendar julian apply imputation rule
 show field color coding
 expand text fields

Fax View:

During duplicate resolution display image review dialog:
 when the existing record is loaded
 when the revised record is saved

Screen Options:

Background color: black white color
Background type: Default

Auto Logout:

Exit after 10 minutes of inactivity

OK Cancel

Select Preferences from the File menu to view and change your iDataFax preferences. Preferences are user and study specific. The default settings are illustrated here. Any changes are applied immediately and preserved across sessions. Some preferences may refer to parts of iDataFax for which you do not have permission, and will thus be irrelevant. A description of each of the preference settings appears below.

12.1. Data Window

- expand all assessments when a patient binder is opened - if this preference is not checked patient binders will open to show all study assessments but all assessments will be closed, whereas with this preference checked all assessments are also opened to show the CRF pages they contain.
- display first page when an assessment is opened - this preference determines whether the data screen is automatically loaded with the first page of the assessment when a new assessment is opened.
- advance to next field after current field is completed - if this preference is not selected the focus remains on each field until the user presses the Tab or Return key to advance to the next data field.
- open first task record when task set is built - if this preference is selected the first data record is opened automatically when a new task is selected, otherwise users must open the first task record manually by selecting the desired patient binder.
- warn before opening next patient when traversing task records - this preference is only relevant to users who have access to record selection tasks and is used to ensure that the user is aware of transitions from records for one patient to records for a different patient.
- retain scroll position when traversing task records - this preference is only relevant to users who have access to record selection tasks. It is useful when the task involves a review of fields near the middle or bottom of the page, as it avoids the normal scroll to the top of each new page.

12.2. Image Window

- auto open/close as image is available/unavailable - if this preference is selected faxed/scanned CRF pages (or other images) are automatically displayed when a page having such images is selected. When this preference is selected the display method is determined by which of the following options is selected.
- toggle screen between data and image views - switching between data and image views is performed using the blue image button in the bottom right corner of the screen, but the data view will always appear on switching to a new page in the patient binder.
- split screen: data left, image right - occurs if an image is attached to the current data record
- split screen: image left, data right - occurs if an image is attached to the current data record
- split screen: data top, image bottom - occurs if an image is attached to the current data record
- split screen: image top, data bottom - occurs if an image is attached to the current data record
- Sticky toggle: retain data or image view across records - switching between data and image views is performed using the blue image button in the bottom right corner of the screen, and the last selection will remain in effect on switching to a new page in the patient binder.

12.3. Record List

- Show assessment number:label, number, label - this preference determines how assessments are identified when a patient binder is opened. Each patient assessment has both a number and a descriptive label. Both number and label or only one of these can be displayed.
- Show page number:label, number, label - this preference determines how the pages within patient assessments are identified when an assessment is opened. Each page has both a number and a descriptive label. Both number and label or only one of these can be displayed.
- Show site number:label, number, label - this preference determines how sites appear in the record list. Each site is assigned a number and a descriptive label during study setup. Both number and label or only one of these can be displayed.

12.4. Query Defaults

- Use: external or internal - this preference is only relevant to users who are allowed to create new queries and determines the default usage type set in the query creation dialog. External queries are directed to the clinical sites, while internal queries are not.
- Type: clarification or correction - this preference is only relevant to users who are allowed to create new queries and determines the default response type set in the query creation dialog. Clarification queries are used to request a reply to a question, while correction queries are used to request a correction to one or more data fields.

12.5. List View

- show field name: generic or unique, and number:name - this preference is used to specify column labels for the list view data table. These labels can display the generic or unique field name, and may also include the field's data entry tab order number.
- show coded field: code or label - this preference determines whether fields that have codes and labels, e.g. 1=male, 2=female, display the code or the label.
- show date field: default, calendar, julian, and apply imputation - dates may be shown exactly as entered into the study database (default), in calendar format (with 4 digit years), or as a julian number. In addition any imputation rules that have been specified for partial dates may be applied if the calendar or julian format is selected.
- show field color coding - each cell in the data table may be displayed in the same color used in Data View (red=field is illegal or blank but required, etc., see Help-Color Coding).
- expand text fields - if cells in the data table are too small to display the entire data field selecting this preference will expand the cell and display all that it contains when the cell is selected.

12.6. Screen Options

- Background color: black, white or color - this preference determines whether data fields are displayed on a black, white or color background. Color is only useful if color CRFs have been imported in DFsetup to create the data screen backgrounds. Black is recommended, even with color CRF backgrounds, to reduce eye strain and make data fields and color coding stand out more clearly.
- Background type - different versions of some or all of the CRF pages can be imported during study setup. For example, some CRF pages might be available in multiple languages. This preference allows the user to select the version of the CRFs to be used for both the data entry screens and when printing CRFs or creating PDFs.

12.7. Fax View Options

When a CRF page is refaxed users perform duplicate resolution by loading the existing data record, comparing it with the new fax image, and correcting any data fields that need to be updated. During this process users can select the image count button at the bottom of the screen to review the previous and new CRF images. Alternatively either or both of the following preferences can be used to display the image review dialog automatically:

- when the existing record is loaded - useful if you always want to compare the old and new CRF images before reviewing and correcting any data fields.
- when the revised record is saved - use this option if you want to delay image comparison until after reviewing, correcting and saving the data record.

12.8. Auto Logout

- Exit after 10 minutes of inactivity - study administrators can specify a default and maximum time period and thus the default may be something other than 10 minutes. Users may change the default to any value up to the maximum. An automatic timeout, after a period of inactivity, is needed to meet regulatory requirements and protect patient confidentiality. Remember that any changes to the current page that have not been saved will be lost if a login session times out.

Chapter 13. Appendix

13.1. Terminology

This section explains some of the terminology used in this manual.

Assessment	An assessment is a set of data collection pages which are completed together at a specified time, per instructions in the study protocol. Each assessment represents: a clinic visit, a home visit, medical tests, medical records, patient questionnaires, etc.
Electronic Signature	Your electronic signature has two parts - your login name and your password. You must specify both parts when you log into the study's DataFax server. All data collected is recorded under your electronic signature and can be traced in DataFax audit trail reports.
Final	A page can be saved with status Final if there are no illegal values or unanswered queries from the study coordinating center. iDataFax marks Final pages with a green check mark. (see also Incomplete and Pending)
Incomplete	A page can be saved with status Incomplete if it has any fields which are incomplete or illegal, or outstanding queries. iDataFax marks Incomplete pages with a red X. (see also Final and Pending)
Page or Plate	<p>Page and plate are 2 terms used interchangeably to refer to a logical grouping of data items (aka data fields) presented with a layout determined by the study sponsor, to fit on a single sheet of paper. Each page may stand alone, or pages may be grouped into multi-page forms. A collection of pages (or forms) constitute an assessment, and a collection of assessments constitute the patient binder which holds all study data for an individual patient.</p> <p>In a paper based approach to data collection, these pages are printed, completed and faxed to the DataFax system. When using an EDC approach, the same pages are completed using iDataFax.</p>
Patient	An individual participating in a research project for whom data will be collected is a patient. Within iDataFax , patients are identified by patient ID number (a unique numeric identifier), according to conventions established by the study coordinating center.
Patient Binder	A patient binder contains all of the required and optional data collection forms used to collect study data for an individual patient. Within iDataFax , patient binders are displayed in a list by patient ID number, with an associated icon that shows whether the binder is empty or contains recorded data, and whether that data is currently complete, incomplete or pending.

Pending	<p>During new data entry a page can be saved with status Pending to indicate that you are not finished with it and plan to return to it shortly. These pages are saved at work flow level 0 and do not move to higher levels until they are saved with status Final or Incomplete. Typically pending pages at level 0 will not be reviewed by the study coordinating center until they progress to level 1 or higher.</p> <p>Pages which have progressed beyond level 0 can not return to level 0, but they can be reset to status Pending to indicate that there is something seriously wrong which needs to be corrected before the data can be used in statistical reports. The ability to demote records this way is restricted to users with Data View - with Select permission. iDataFax marks Pending pages with a yellow dash. (see also Final and Incomplete)</p>
Query	<p>The study coordinating center may add a query to any data field to request a correction or clarification. iDataFax colors fields with an outstanding query blue. When a reply is provided to a query, or a reason is added to explain the field, the color changes to orange, and when the field has been corrected, or the reply or reason have been approved, the color changes to green.</p>
Reason	<p>A reason explaining a data value can be added to any data field. This is particularly useful as a way of explaining unusual values and thereby avoiding a data query from the study coordinating center. iDataFax colors fields with a new reason orange and gives them a Pending status. If the coordinating center accepts the reason, the field color changes to green and reason status changes to Accepted. If they do not accept the reason, field color changes to blue and the reason status changes to Rejected. A reason can be modified, which starts the review process over again.</p>
Save	<p>None of the changes you make to a page are sent to the study DataFax server until you click one of the 3 Save buttons at the bottom of the screen: Final, Incomplete, or Pending. If you leave the computer without saving your work, iDataFax will time-out after a few minutes and the changes you made will be lost. However you will be warned that this has happened the next time you connect to the study and you can opt to return to the same page.</p>

13.2. Common Error and Warning Messages

This section describes some common messages that users may encounter during their use of **iDataFax**.

Table 13.1. iDataFax Login

Message:	Server Unreachable! - Check server and/or your network connection!
Possible Cause:	There is no internet connection available or server address/name entered is invalid.
Solution:	Confirm that your internet service is functioning properly. Confirm that you have correctly typed the DataFax Server name in the login dialog. Otherwise, contact your iDataFax Study Coordinator or System Administrator.

Message:	Unable to connect to DataFax server! - Check if DataFax EDC Service is running!
Possible Cause:	DataFax is not running on the specified server or DataFax EDC Service is not running.
Solution:	Contact your iDataFax Study Coordinator or System Administrator and confirm that the DataFax Server and DataFax EDC Service is running properly.
Message:	Unable to get a list of studies from the server.
Possible Cause:	The user has not been given access to any studies in the DFsystem tool or the iDataFax server or DFedcservice is not running.
Solution:	Contact your iDataFax Study Coordinator or System Administrator.
Message:	Error: Unable to load study setup file
Possible Cause:	The study Setup file does not exist or is empty.
Solution:	Contact your iDataFax Study Coordinator or System Administrator.
Message:	Unable to load patients. Please contact iDataFax system administrator.
Possible Cause:	The DFcenters file does not exist or is empty, or the user does not have permission to access patient numbers due to restrictions defined in their DFsystem user account.
Solution:	Contact the iDataFax Study Coordinator or System Administrator.
Message:	Unable to load assessments. Please contact iDataFax system administrator.
Possible Cause:	The DataFax DFvisit_map does not exist or is empty, or the user may not have permissions to access the necessary visits and/or plates due to restrictions defined in their study role.
Solution:	Contact the iDataFax Study Coordinator or System Administrator.

Message: It appears that your computer's date and time are incorrect. **iDataFax** has been set to view only mode until the date and time are fixed and you login again.

Possible Cause: Either **iDataFax** can not obtain a valid date and time from the computer on which it is running, or the value obtained is more than 48 hours ahead or behind the value obtained from the study database server.

Solution: Update the date and/or time on the computer that is running **iDataFax**.

Table 13.2. Data Entry

Message: You have been automatically logged out of your current session.

Possible Cause: The user's iDataFax session has been inactive for the number of minutes specified by the user's Auto Logout setting.

Solution: Each user can customize the number of minutes after which the iDataFax auto logout takes effect. The default Auto Logout setting may be changed by logging into iDataFax, opening the Preferences dialog from the File menu and changing the Auto Logout preference.

Message: The definition of this page has changed. This page needs to be reviewed centrally before you can access it again. Please notify your study coordinator.

Possible Cause: This message arises when the number of fields on a page has been changed so that its definition no longer matches the data already existing in the database.

Solution: The data records for the page will need to be reformatted before you can access them. Contact your iDataFax Study Coordinator or System Administrator.

Message: This page can not be saved with status Final because of problems identified by edit checks.

Possible Cause:	Edit checks that are set to execute upon saving the page may cause certain data fields to be marked with an outstanding query or an illegal data value. If either or both exist, it will not be possible to save the page with status Final.
Solution:	Review the page for any outstanding queries (blue fields) and/or illegal data values (red fields), and either correct those problems or save the page using <code>Pending</code> or <code>Incomplete</code> status.
Message:	Error in saving record changes. Cause: A valid date/time stamp could not be created.
Possible Cause:	Either iDataFax can not obtain a valid date and time from the computer on which it is running, or the value obtained is more than 48 hours ahead or behind the value obtained from the study database server.
Solution:	Update the date and/or time on the computer that is running iDataFax .
Message:	Field field_name: storing value field_value (which contains illegal/extra characters) into variable has altered the value.
Possible Cause:	The field value stored in the study database is different from the value displayed in the field widget on screen. The database value may not match the field format, or may be larger than the current field store length. The study setup specifications may have been changed to make previously entered values incompatible with the current field specifications.
Solution:	Reenter the specified fields with values compatible with the current field properties and save the record to the study database.

13.3. Programs

This section describes the standard DataFax programs available for both adhoc record selection and task definition.

13.3.1. DFmkdrf.jnl - make DataFax DRF file from study journals

Program DFmkdrf.jnl processes the study journal (audit trail) files and can be used to identify records entered by specified users during specified times with specified criteria. Its output includes all records that match the specified criteria, but any given user will only see those records they have permission to get. The program usage message follows.

DFmkdrf.jnl - make or load a DataFAX Retrieval File

```
USAGE: DFmkdrf.jnl [ DFNUM ] [-t date1-date2 | -days #]
        [-u include_users] [-xu exclude_users]
        [-v levels] [-s statuses] [-I IDs] [-S SEQs] [-P plates]
        [-image yes|no] [-d 1|2]
        [-records #] [-cases #] [-put drfname] [-h header]
        [-get drfname] [-test]
```

OPTIONS:

```
DFNUM          ... DataFAX study number may be 1st argument or set in
-t yymmdd-yymmdd ... selection period: dates during which records were saved
-days #        ... select records saved in the past # days
-u list of users ... select records saved by specified users
-xu list of users ... exclude records saved by specified users
-v # #-#       ... select records saved at specified validation levels (0-7)
-s status      ... select statuses: final,incomplete,pending,lost
-I # #-#       ... select patient ID numbers
-S # #-#       ... select sequence/visit/assessment numbers
-P # #-#       ... select plate numbers
-image yes|no  ... select records with images only, or without images only
-d 1           ... deselect if criteria no longer apply at end of selection period
-d 2           ... deselect if criteria no longer apply now (journal's end)
-records #     ... maximum number of data records to be included in the drf file
-cases #       ... maximum number of patients to be included in the drf file
-put drfname   ... write output to a specified drf file in the study drf folder
-h header      ... include a descriptive header/title for the drf file
-get drfname   ... load an existing drf file from the study drf folder
-test         ... check and display record selection options then quit
```

NOTES:

- DFNUM does not need to be specified when running DFmkdrf.jnl in iDataFAX; or if environment variable DFNUM is set to the study number when running shell scripts.
- Input: DFmkdrf.jnl reads the study journal files and thus will not generate correct output if any of the journals have been removed or truncated.
- Output: a DRF record is created for journal records that meet all selection options at some point in the specified time period:
 - d 0: even if these records no longer meet the selection options (default), or
 - d 1: if they still meet the selection options at the end of the time period, or
 - d 2: if they still meet the selection options now.
- A DRF record is not created for any record deleted after meeting the selection criteria because a deleted record can not be retrieved from the study database.
- If the keys (ID,Visit,Plate) are changed after a record meets the selection criteria, a DRF record will be created for both the old keys and the new keys if they both correspond to a current data record.
- The record selection period may be specified using:


```
yymmdd-yymmdd or yymmdd-today ... a date range, or
yymmdd or today ... a single date
```
- If the -drf option is not specified output is written to standard out.
- If the -cases and -records options are both specified, -cases has priority

EXAMPLES:

Output DRF records for data records in study 253 that were saved with associated images by jack or dianne at level 1 in Nov. 2007, regardless of whether these records were subsequently saved by someone else or at different levels or without an associated image.

```
DFmkdrf.jnl 253 -image yes -u jack,dianne -v 1 -t 071101-071130
```

Repeat the above but only create DRF records if the selection criteria remain in effect now, i.e. deselect any records that no longer meet the selection criteria at the end of the audit trail.

```
DFmkdrf.jnl 253 -image yes -u jack,dianne -v 1 -t 071101-071130 -d 2
```

Create a DRF file named myTest.drf for data records in study 253 which were saved in the past 10 days with visit numbers 1,2 or 50-59 and record status = incomplete by someone other than the current user.

```
DFmkdrf.jnl 253 -days 10 -S 1,2,50-59 -s incomplete -xu whoami -put myTest.drf
```

Load DFUnexpected.drf, a DRF file created by DF_QCupdate and stored in the study drf folder.

```
DFmkdrf.jnl 253 -get DFUnexpected.drf
```

13.3.2. DFmkdrf.ec - make DataFax DRF file from edit checks

Program DFmkdrf.ec creates a DFbatch file and runs it to identify records with edit checks that would display a message, create or edit a query or modify a data field were they to be run interactively. No changes are made to data or metadata. The only output is a DataFax retrieval file listing the records that met the specified criteria. Any given user will only see those records they have permission to get. The program usage message follows.

DFmkdrf.ec - make DRF records by running DFbatch to execute specified edit checks

USAGE: DFmkdrf.ec [DFNUM] -P plates -E editchecks [-v levels -s statuses -I IDs -S SEQs]
 [-P another batch specification] [-which] [-warn]

OPTIONS:

DFNUM ... DataFax study number
 -P Plates ... plate specification starts each new batch specification
 -E Edit Checks ... edit check names to be executed on the specified plates
 -v # #-# ... select records by specified validation levels (0-7)
 -s status ... select records by record status final,incomplete,pending,lost
 -I # #-# ... select records by patient ID numbers
 -S # #-# ... select records by sequence/visit/assessment numbers
 -which msg qc data ... determines EC events that trigger creation of a DRF record
 -warn ... display any warning messages generated by DFbatch
 -u ... print this usage message and quit

NOTES:

1. iDataFax uses environment variable DFNUM which is set to the current study number. Only specify DFNUM on the command line when running DFmkdrf.ec from a shell script or terminal session where DFNUM is not set.
2. Each batch specification must begin with the -P and -E options, in that order.
3. Use -E ALL or -E all to include all edit checks on the specified plates.
4. The -which option determines the conditions under which a DRF record is created. Edit checks are executed with APPLY=none so no changes are made to the database. Instead a DRF record is created for the current page if the edit check would do the following with APPLY turned on:
 msg - execute a message function: dferror, dfwarning, dfmessage
 qc - create a new QC note or edit an existing one
 data - modify a data field
 The default value for the -which option is msg qc data, i.e. all 3 triggers apply.
5. The -which option applies to all batches. Only 1 -which option can be specified.
6. Status can be specified using 3.7 or 3.8 terminology, like this:
 -s clean,dirty,error,lost or -s final,incomplete,pending,lost
7. Temporary files are created in the study work directory and then removed.
8. User permissions are applied.

EXAMPLES:

Write DRF records to standard out for study 253 if edit check test1 or test2 on plates 1-3 would display a message, add or modify a query or make any changes to a data field.
 DFmkdrf.ec 253 -P 1-3 -E test1,test2

Same as the first example but only trigger these edit checks on plate 1 and only for data records that have status final and are at validation levels 3-6.
 DFmkdrf.ec 253 -P 1 -E test1,test2 -s final -v 3-6

Same as previous example but trigger test1 on all plate 1 records and test2 on plate 2-3 records that have status final and are at validation levels 3-6.
 DFmkdrf.ec 253 -P 1 -E test1 -P 2-3 -E test2 -s final -v 3-6

Same as the previous example but edit checks test1 and test2 only generate a DRF record if they would have created a new QC note or modified an existing QC note.
 DFmkdrf.ec 253 -P 1 -E test1 -P 2-3 -E test2 -s final -v 3-6 -which qc

Create DRF records for any edit check that would change a data field.
 DFmkdrf.ec 253 -P 1-499 -E ALL -which data