



Getting Started with iDataFax (v2016.0.2)

Clinical Research Unit (CRU)



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Definitions/Acronyms/Abbreviations

Term/Acronym	Definition
Centre	Participating Centre
CRF	Case Report Form
CRU	Clinical Research Unit
Patient Binder	Compilation of all available CRFs for a patient within iDataFax
QC	Quality Control

System Overview

iDataFax is a remote data entry tool that allows participating centres to enter their data electronically. This type of data entry is commonly referred to as Electronic Data Capture or EDC. iDataFax also allows centers and collaborative groups to view the data that has been submitted. This manual explains the procedures for viewing data that is entered into iDataFax. Please refer to the iDataFax User Guide (Release 2016.0.2) for full information.

System Requirements and Recommendations

- Internet Connection
- Operating System: iDataFax is available for direct installation on Windows XP, Windows 7, Windows 8+, Mac OS X, Solaris, and Linux. If you plan to use iDataFax on more than one computer you will need to install the application on each computer.
- Ability to download and install the iDataFax software (**v2016.0.2**)
NB: Please note if you had previously installed v2014.1.2, it is recommended to uninstall before attempting to install the new version, v2016.0.2.

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 data monitor or coordinating center, thus saving you time in the long run!**

Installing iDataFax

The iDataFax installer package may be downloaded from a link provided in an email from the Clinical Research Unit (cru@ucalgary.ca). A download window is displayed; click on "Run" to download and install the iDataFax software (v2016.0.2).

Please find below the links to download and install the software version (v2016.0.2):

For Windows & Mac:

[iDataFax v2016.0.2 download-Windows](#)

[iDataFax v2016.0.2 download-OSX](#)



Please note, after you have successfully installed iDatafax, you will need to enter the Server Name: **datafax.cru.ucalgary.ca**

Logging in to iDataFax

Please contact your site coordinator/manager for how to get a user account.

You will be prompted to change your password the first time that you log in. Contact cru@ucalgary.ca for lost or forgotten passwords. A new password will be sent to you within 2 business days.

Login Procedure

- 1) Double click on the iDataFax icon on the desktop to start iDataFax. The Login box will appear. Verify the Server field displays “**datafax.cru.ucalgary.ca**”. If not, type it in.
- 2) Enter your CRU assigned Login Name and Password.
- 3) Click “Login.” You have officially logged in to iDataFax. Upon login, a list of trials to which the user has access will be displayed.
- 4) Once connected, the iDataFax User Toolbox is displayed. To access a trial, either double click on it or click once on the trial and then click “OK”. If you do not open a trial and the screen is inactive, you will be logged out after one minute and you will need to log in again.

Time-out Procedures

To keep patient data secure, iDataFax will **automatically log you out** if the program has been inactive for longer than 5 minutes. If iDataFax is the active application on the screen, any keyboard or mouse activity will reset the timer.

When you are automatically logged out, the Auto Logout box will appear. To return to iDataFax, click “Login again”. To exit iDataFax, click “Exit.”

If you are logged out and then log back into the same study, a dialog box will be displayed. You will be allowed to return to the same screen you were in before you were logged out. To do so, click “Yes” to return to the last record you accessed.

Exiting iDataFax

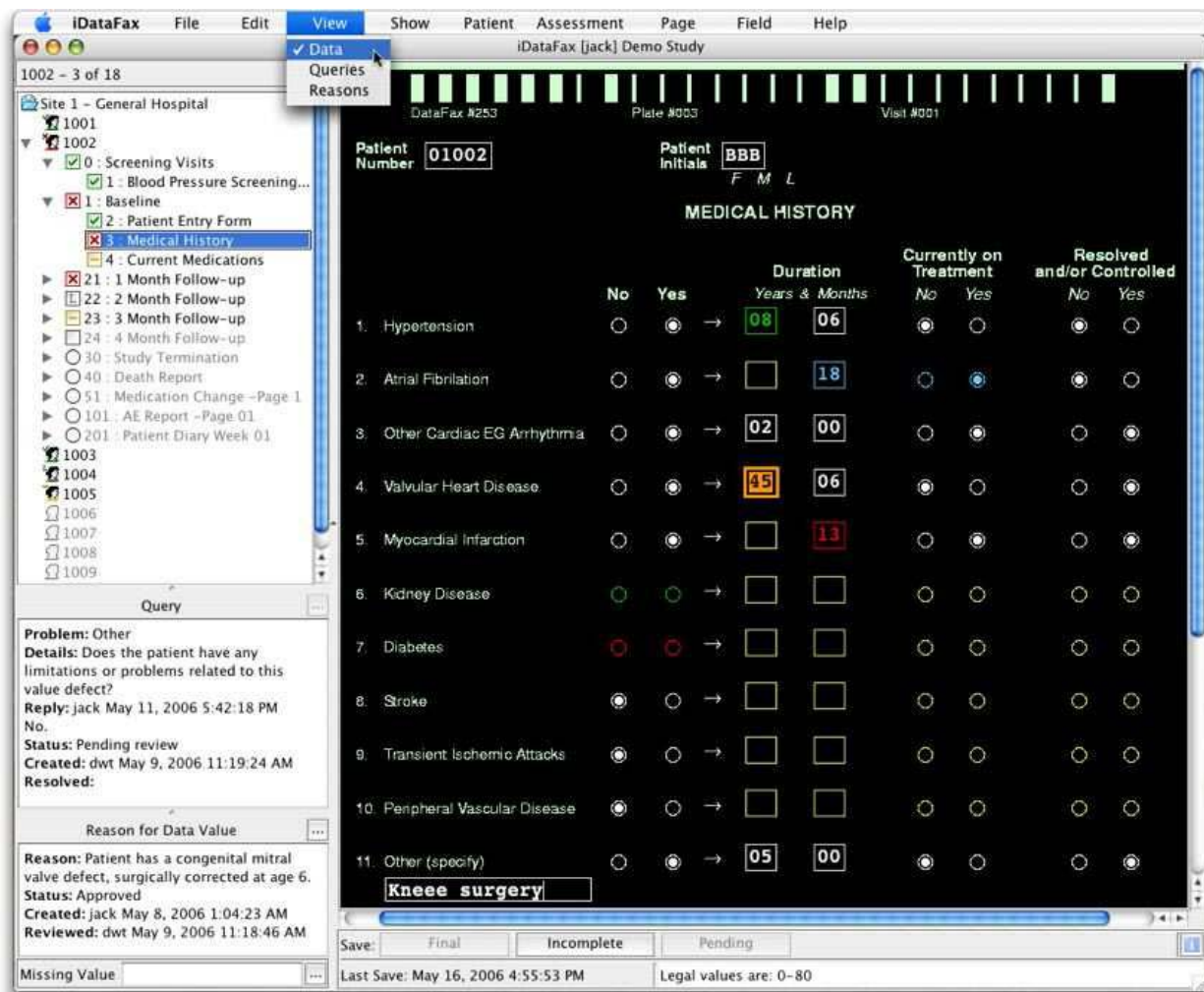
Closing out of the Study vs. Exiting DataFax

To change to a different study (close out of the current study), select “File” from the menu bar and then select “Close Study”. This will close the current study and display the List of Trials (available to you) tool box. You will be able to select another Trial (if you have permission to access more than one trial). Selecting “Exit” from the drop-down menu will exit the iDataFax program.

Navigating within iDataFax

Patient Binder

The Patient Binder provides a list of Centers, Patients, and available CRFs for the trial. iDataFax will display icons next to each patient and CRF that will indicate the current status of that item. These icons show the user which patients or CRFs need additional information.



The screenshot shows the iDataFax Patient Binder interface. The left sidebar displays a tree view of forms for Site 1 - General Hospital, including Screening Visits, Baseline, Patient Entry Form, Medical History, Current Medications, and various follow-up visits. The main area shows patient information for Patient Number 01002 and Patient Initials BBB. Below this is a table titled "MEDICAL HISTORY" with columns for Disease, No, Yes, Duration (Years & Months), Currently on Treatment (No, Yes), and Resolved and/or Controlled (No, Yes). The table lists 11 conditions, with "Knee surgery" entered in the "Other (specify)" field. The bottom of the interface includes a "Save" section with buttons for Final, Incomplete, and Pending, and a "Last Save" timestamp.

Disease	No		Yes		Duration Years & Months		Currently on Treatment		Resolved and/or Controlled	
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Years	Months	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1. Hypertension	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	08	06	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Atrial Fibrillation	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>		18	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Other Cardiac EG Arrhythmia	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	02	00	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Valvular Heart Disease	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	45	06	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Myocardial Infarction	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>		13	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Kidney Disease	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Diabetes	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Stroke	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Transient Ischemic Attacks	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Peripheral Vascular Disease	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Other (specify)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	05	00	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Reason for Data Value: Reason: Patient has a congenital mitral valve defect, surgically corrected at age 6. Status: Approved. Created: jack May 8, 2006 1:04:23 AM. Reviewed: dwt May 9, 2006 11:18:46 AM.

Save: Final Incomplete Pending. Last Save: May 16, 2006 4:55:53 PM. Legal values are: 0-80.

Forms Order

When a patient is randomized, all forms for that patient, for the life of the trial are available in the patient binder. Some forms may not pertain to a specific patient's treatment and therefore, do not need to be completed. If CRFs are submitted out of the appropriate sequence of visits, queries will be generated.

Color Coding

iDataFax uses different colors to provide information about each field. The chart below explains the colors that appear in iDataFax.

Color	Meaning
White	Acceptable value
Red	Illegal value or blank required field
Yellow	Blank optional field
Blue	Unresolved query or a rejected reason
Orange	Query or reason has been answered by a Centre, but has not yet been reviewed
Green	A resolved query , an accepted reason, or a predefined missing value code

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 & password, all of which will be provided by the study coordinating center (see 'Login Procedure', page 3).

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.

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

There are two methods in which you can enter data: 1) Fax & verify data entry, and 2) Manual Data entry. You can use either one, or a mixed combination of both.

Option 1 – Faxing CRF's

Fax completed CRF's to: **1-877-654-8323**

iDatafax has the ability to recognize and import data from the paper CRF's you complete and store as source, this is called Intelligent Character Recognition (ICR).

The ICR can **only** read: check boxes, numerical fields, date fields, and visual analog scales.


Text must be entered manually. Data fields will be left blank if ICR encounters an ambiguous entry (e.g. more than one response checked where only one is allowed) or if it reads a numerical value which does not pass its legal values test. Text is NEVER recognized, and must always be entered manually.

Each CRF page received by fax is read by the ICR software to create an initial data record which is assigned a validation level of **zero** and a status of new, and then stored in a new fax record queue.

ICR ≠ data entry!

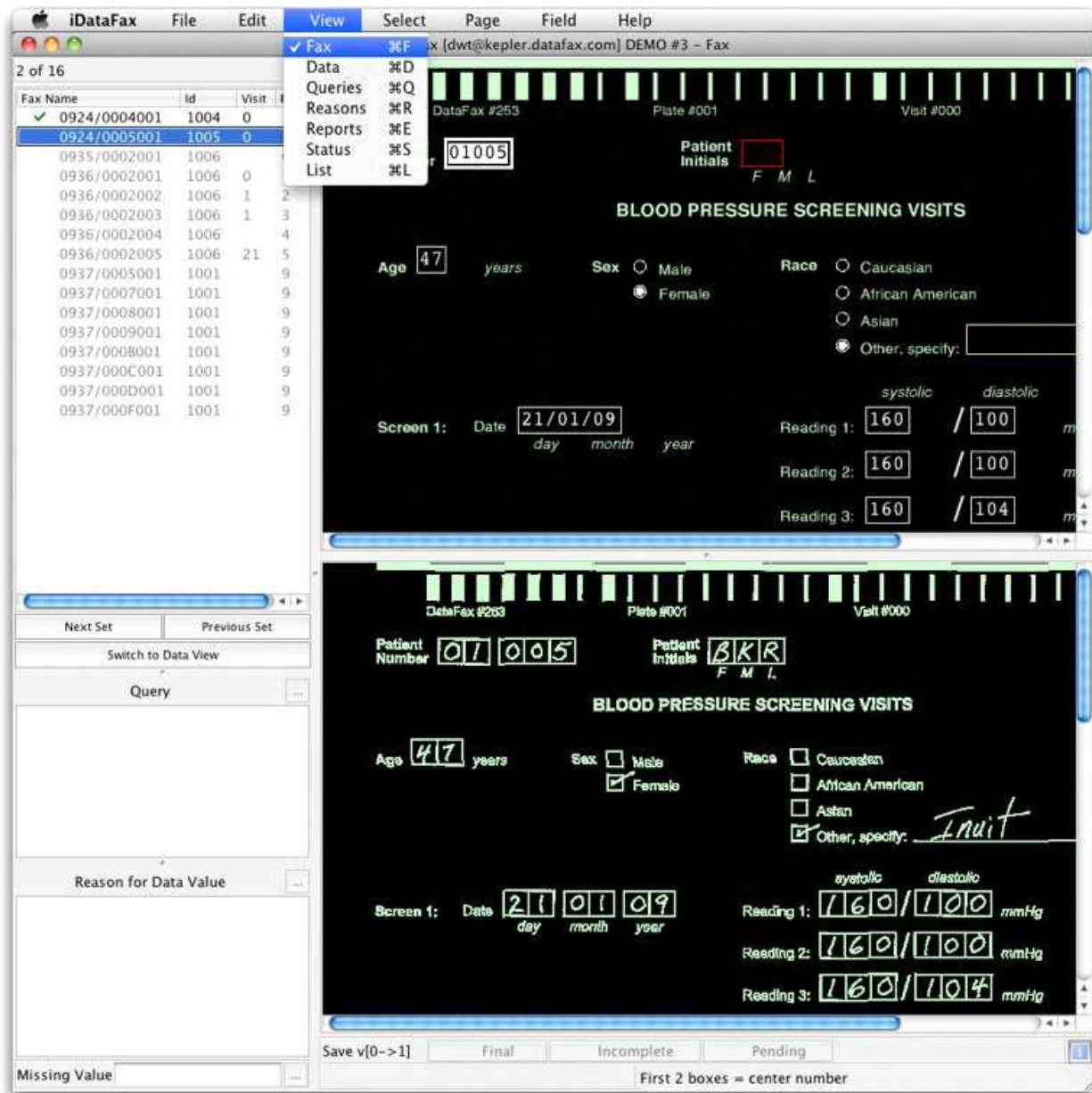
The data record **does not** enter the study database **until** it has been reviewed and validated to a higher validation level - this step is typically performed by a data entry clerk working at validation level 1. The validation of new records involves:

- Retrieving a set of new fax records.
- Displaying the faxes in the split screen windows (data right and fax left).
- Comparing what is in the data entry window with what is on the faxed image of the CRF.
- Editing the data window to enter text, completing any fields left blank or misread by the ICR software.
- Flagging any problems (e.g. missing data) with QC notes.

To get the fax images, you must change your view to **Fax view** by selecting it from the View menu in the menu tool bar. A box for 'Record Retrieval' of faxes will pop-up (*or* if it doesn't, click 'Select', then 'New Record Retrieval Dialogue'). As this is the initial data entry, select '1' as the Sign off Level, and ensure 'Faxes' & 'Oldest' are selected, and then hit 'OK'. This will pull up the faxes waiting to be reviewed in the left hand navigation pane. You can see each faxed page will have a: Fax ID, ID, Visit, Plate. By selecting the first record/fax you wish to work on will show you the image in the main screen area. You can toggle between the Data and Fax views by clicking the  at the bottom right hand corner (or if you have set your Preferences (under File - Preferences) as Fax view: split screen, you will see both the data view and fax image side-by-side). Work through each fax record, comparing the values to the image of the faxed CRF, and once satisfied, hit save as Final and **release the record (Important!** If you do not release the records, they do not make it into the database!).

Remember, **ICR ≠ data entry!**

Correcting Data Entry Errors: If you see an obvious data entry error or omission, correct it now. If you think that a data field needs correcting (but feel that the value is open to interpretation, or you are not sure what value should be entered), you can flag it with an internal quality control note. Since corrections should be fairly infrequent (as the ICR should pick up all the checkboxes to assist you) this review should proceed quickly. However, vigilance is critical. If you find yourself losing the ability to concentrate, stop and do something else, or take a break. At a minimum you should take a break for at least 5 minutes every hour.



Option 2 – Manual Data entry

If you are not already in the **Data view**, select it from the View menu in the menu bar. 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 simply click/type to enter data, add reasons to explain unusual values, and reply to outstanding queries from central office.

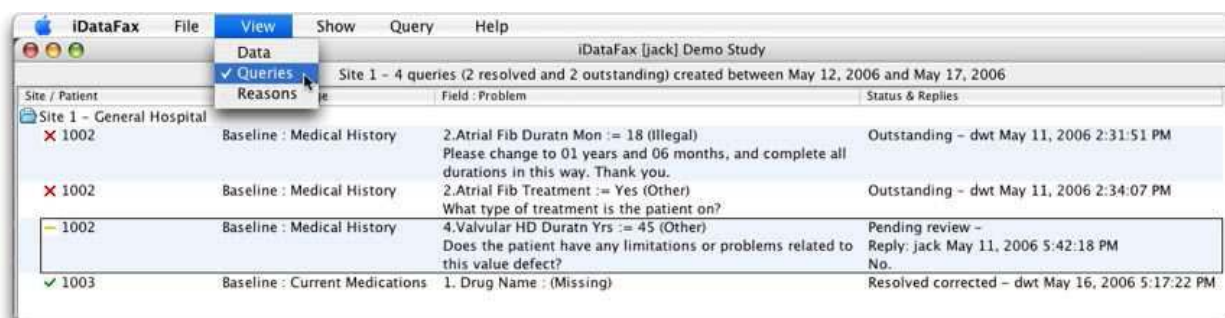
Saving your work

When you are finished with a CRF/page, to save your work in the study database, 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).

Checking for Queries

The **Queries View** lists data queries from the study Coordinating Center, or from a Data Monitor. 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.

To view a query: select from Queries from the 'View' menu on the tool bar. A list of all queries for the study will be displayed. A number of filters may be used to specify which queries are displayed. Double clicking a query will open the associated record and patient binder in the data window. To exit **Query View** and return to all viewing data, select **Data View** from the View menu on the tool bar.



User Support and Contact Information

Need help? The iDataFAX User Guide is always available to you, located under 'Help – Topics'. This should be the first place you look if you have a question about datafax.

For questions related to study-specific issues, contact the central site of your trial.

For technical questions about iDataFAX or connection issues, contact the CRU user support at:

cru@ucalgary.ca

Reference

DF/Net Research, Inc. (2015). iDataFAX User Guide