

# SAFETY

Surveillance After Extremity Tumor Surgery

## DataFax Manual and Data Submission Guidelines

Version 1.0

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## Document History

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## 1.0 Introduction

The DataFax Manual and Data Submission Guidelines is a guide for study personnel at clinical sites participating in the **Surveillance AAfter Extremity Tumor Surgery (SAFETY)** trial. The purpose of this document is to facilitate the consistent implementation of the DataFax electronic data capture (EDC) system. Clinical site personnel should review this document prior to beginning study enrolment and refer to it when questions arise. If clinical site personnel have questions regarding participant thoracic imaging, they should contact the Project Manager at the Methods Center via email and / or telephone.

## 2.0 Access and Security

### 2.1 Accessing DataFax

#### 2.1.1 Downloading and Installing the DataFax Software

This section applies only to individuals using the DataFax software. To download and install the DataFax software, the following steps should be taken:

1. Go to: <https://healthsci.mcmaster.ca/clarity-datafax>
2. Select the DataFax installation program appropriate for your computer (Windows or Mac) (see **FIGURE 1**).
3. Select the *Run* button and follow the instructions on the screen.

**FIGURE 1.** DOWNLOADING AND INSTALLING THE DATAFAX SOFTWARE.

CLARITY iDataFax Client Software

This page provides the iDataFax client software for download and instructions.

Instructions Download Help & Useful Preferences

**Download**

Be sure to select **only** the appropriate file for your computer.

Current version (2016.0.1)

This is the latest version of the program, and the only one that works with our server.

If you already have an earlier version installed, we recommended you uninstall that before installing this latest version.

| iDataFax  | DFSend  |
|---|---|
| A tool for filling out CRFs electronically.   | A tool for sending PDFs of paper CRFs and source documents directly into DataFax.   |
| <ul style="list-style-type: none"><li>• Windows (XP Service Pack 3/7/8/10):<ul style="list-style-type: none"><li>◦ iDataFax Installer (39 MB)</li></ul></li><li>• Macintosh (OSX 10.10 and later):<ul style="list-style-type: none"><li>◦ iDataFax disk image (40 MB)</li></ul></li></ul> | <ul style="list-style-type: none"><li>• Windows (XP Service Pack 3/7/8/10):<ul style="list-style-type: none"><li>◦ DFSend Installer (19 MB)</li></ul></li><li>• Macintosh (OSX 10.10 and later):<ul style="list-style-type: none"><li>◦ DFSend disk image (16 MB)</li></ul></li></ul> |

#### 2.1.2 DFNavigator

This section applies only to individuals using DFNavigator, the online data management portal. We encourage individuals to download the DataFax software identified in **2.1.1 Downloading and Installing the DataFax Software**. If you are unable to use the DataFax software, DFNavigator can be used. No software needs to be installed to use DFNavigator. It can be

accessed on most computers and some tablets. To access DFNavigator, the following steps should be taken:

1. Go to: <https://dfnav.mcmaster.ca/>
2. Enter the name of the DataFax server (fhsdatafax.csu.mcmaster.ca) and your unique login credentials that were provided by the Methods Center.

You should now be able to use DFNavigator. Please follow the instructions in the subsequent sections.

**HELPFUL TIP:** DFNavigator works best with either the Google Chrome or Firefox browser.

## 2.2 Entering DataFax

When you login to the DataFax system, your unique login credentials (username and password) constitute your electronic signature. Your electronic signature is the equivalent of your handwritten signature and, thus, is legally binding.

**REMINDER:** Please do not share your password with anyone. The data entered and modified under your login credentials are your responsibility.

The Project Manager will provide you with a username and password. Each person who has permission to enter or modify data or respond to queries will have their own unique login credentials. You will receive an email from the Methods Center with your unique login credentials. Once you receive your username and password, please login to the DataFax system to ensure that your login credentials work properly and to activate your account. Once you have activated your account, you will not be able to enter data into the SAFETY EDC system until you change your password.

Please notify the Project Manager immediately should there be a change in personnel at your clinical site so that the appropriate accounts can be added and / or disabled. Please send the Project Manager an email with the new site research team member's name and email address. Please also include whether the new personnel should receive Quality Control (QC) reports.

### 2.2.1 DataFax Account Password

Periodically changing your password will help to ensure that only you are using your account. Please select a password that is difficult for others to guess and includes the following features:

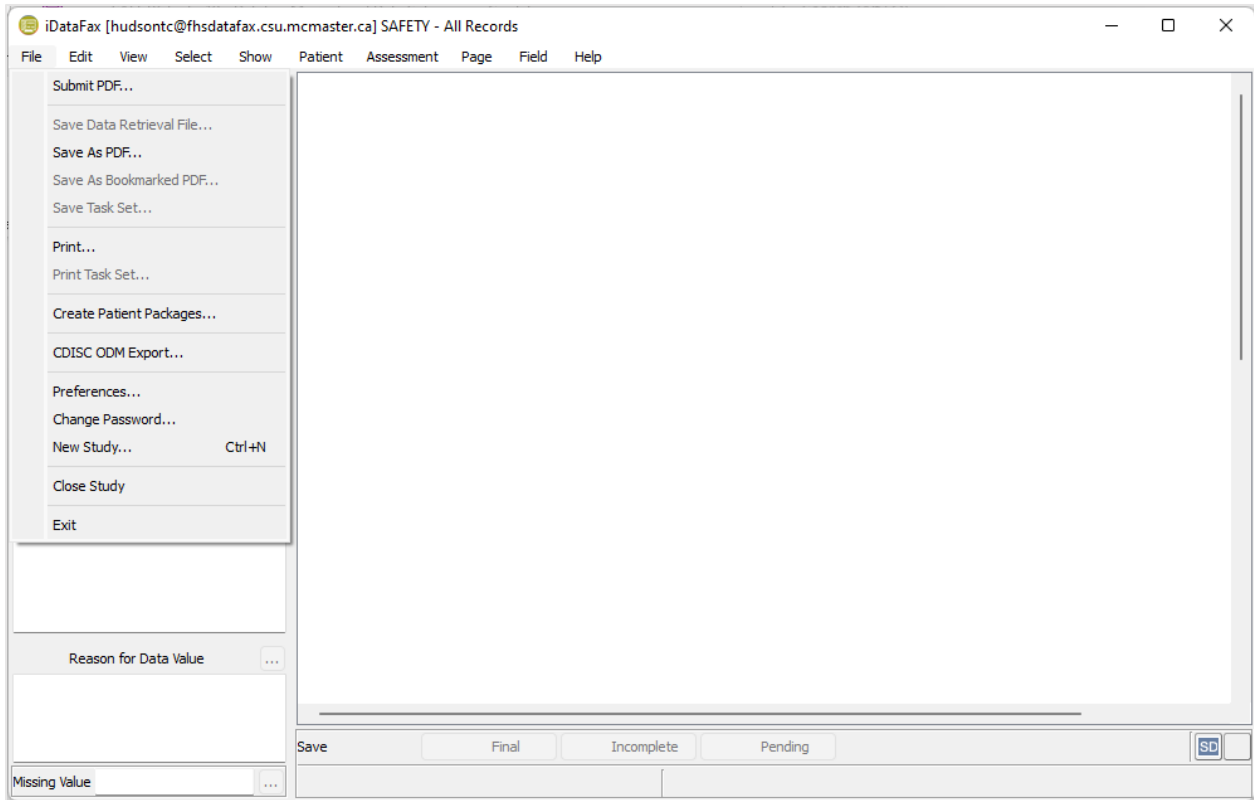
- A minimum of eight (8) characters in length;
- Both upper- and lower-case letters; and
- A combination of letters and numbers.

**REMINDER:** Please change your password if you believe that someone else knows your password and notify the Methods Center immediately if you are concerned about a breach in the security of your password.

The DataFax system will automatically prompt you to change your password every 90 days for security purposes. You can change your password at any time by selecting *Change Password* from the *File* menu (see **FIGURE 2**). Please note that after three (3) failed attempts to enter your

password, you will be locked out for a five (5) minute period before you can attempt your password again.

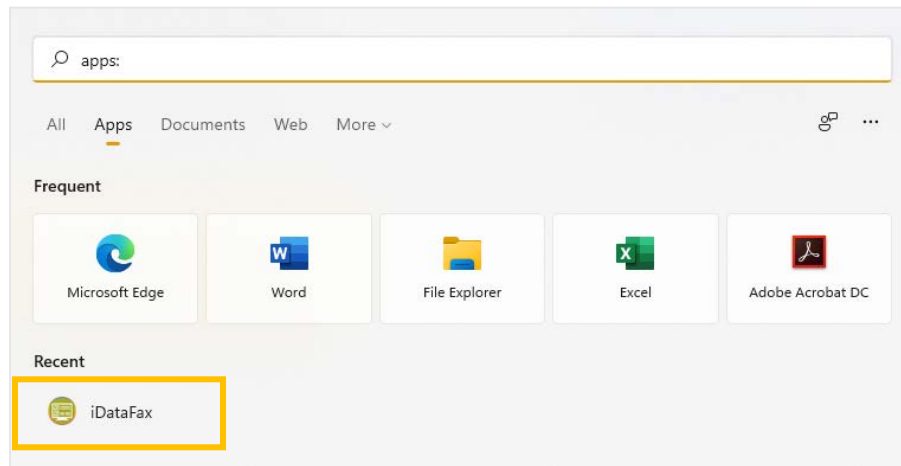
**FIGURE 2.** CHANGING PASSWORD ON THE DATAFAX SOFTWARE.



### 3.0 Using the DataFAX Program

Once you have successfully completed the installation of the DataFAX software, the DataFAX icon should appear on your desktop or applications list (see **FIGURE 3**).

**FIGURE 3.** DATAFAX ICON

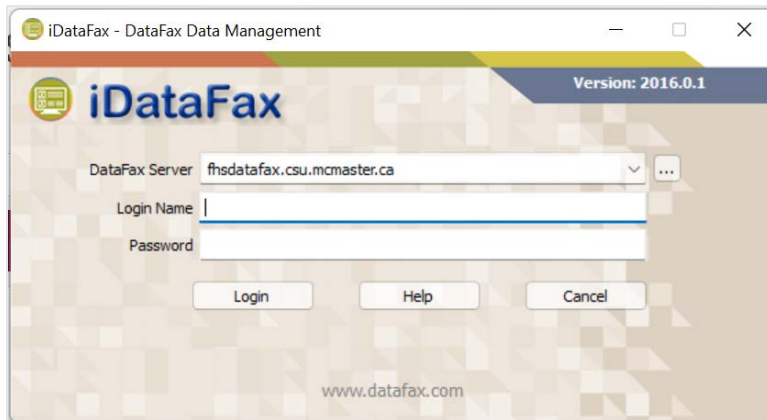


### 3.1 Logging into the DataFax Program

In addition to your unique login credentials, you will also need the name of the DataFax server at the Methods Center to connect to the electronic data capture system. The name of the DataFax server is **fhsdatafax.csu.mcmaster.ca**.

To login to the system, double click the DataFax icon on your desktop and enter the following information (see **FIGURE 4**).

**FIGURE 4.** LOGGING INTO THE DATAFAX PROGRAM

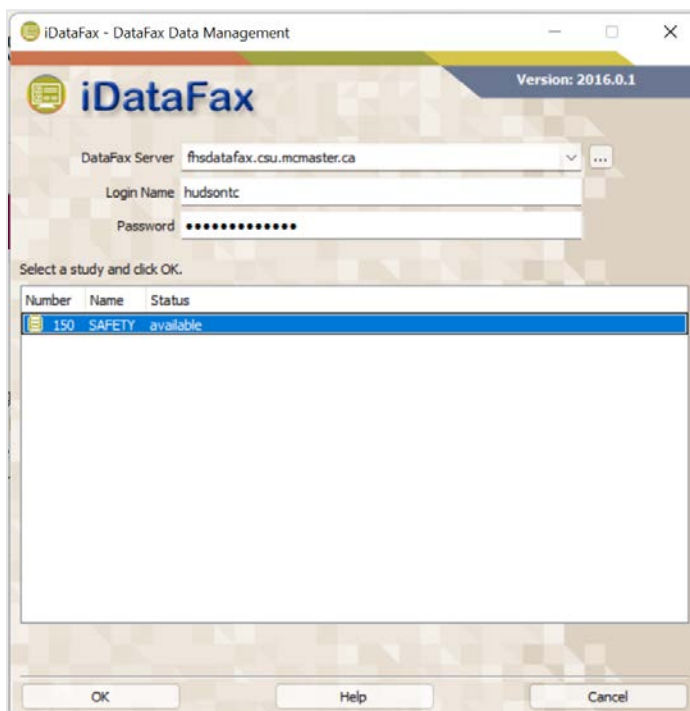


If you cannot log in, confirm that you have entered the correct information. If you still have problems, contact the Methods Center.

### 3.2 Data Entry

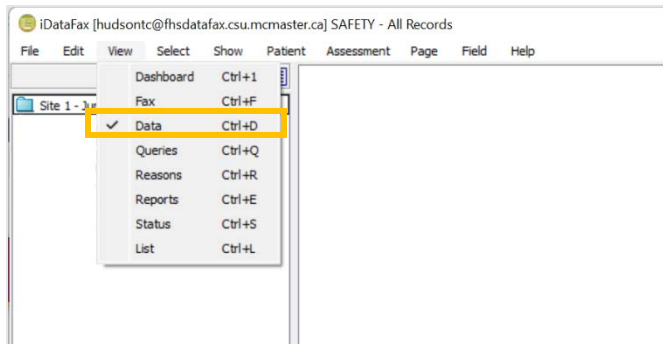
Once you have successfully logged into DataFax, you should see a list of all the studies to which you have access. Double click on *SAFETY* to view the data for your site (see **FIGURE 4**).

**FIGURE 4.** ACCESSING THE SAFETY DATABASE



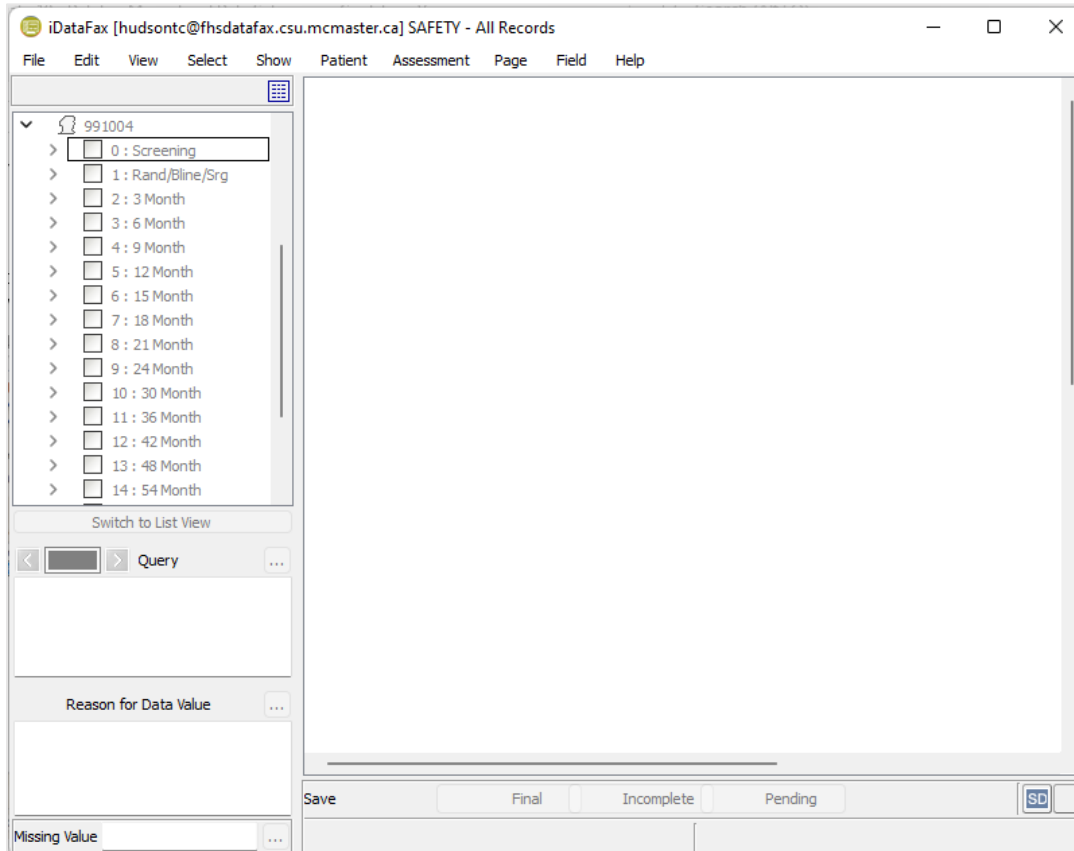
After clicking on *SAFETY*, you should see your site listed on the left and a list of *SAFETY* participants for your site. If you do not see a list of *SAFETY* participants for your site, select *Data* from the *View* menu and double click on your site number to review a list of *SAFETY* trial participants at your site (see **FIGURE 5**).

**FIGURE 5.** VIEWING SITE DATA



All case report forms (CRFs) for a *SAFETY* participant can be found in the participant folder (see **FIGURE 6**). A participant folder is an electronic version of the participant's study binder and is identifiable by the participant's unique Participant ID number. This file contains all the required and optional CRFs for a single participant. Only one participant folder may be open at a time.

**FIGURE 6.** PARTICIPANT FOLDER





## 4.0 Frequently Asked Questions

This section provides clarification and guidance on the study follow-up procedures. Please contact the Methods Center if you have any questions about the study follow-up of a particular participant in the trial.

### 4.1 What are the system requirements for DataFax?

To use the DataFax system, you will require a computer that supports Windows 2000 or newer, or Mac OS X 10.4 or newer. Please contact your institution's Information Technology Department if you are unsure of whether your computer meets the requirements for DataFax.

### 4.2 What are the hardware and software requirements?

Your computer likely already has the required hardware and software installed. If not, this hardware is required before you can install the internet-based data software:

- TCP / IP networking;
- PostScript compatible printer for CRF printing; and
- Class 2 compatible modem, capable of at least 14,400 baud transmission speeds.

Please contact your institution's Information Technology Department to determine if your computer has the relevant hardware and software installed.

### 4.3 What type of internet connection is required?

You can use any internet connection for the DataFax software, but we recommend that you use either a cable or DSL internet connection. The faster the connection, the faster each page will load on your screen.

### 4.4 What size and type of computer monitor works best with DataFax?

A high-resolution display is desirable because it will allow you to view a full CRF page with minimal scrolling to the bottom of the screen. For optimum viewing of all CRFs and images, your monitor should be at least 17" to 21" allowing 1024 x 768 pixels or better.

### 4.5 How much disk space is required to run the DataFax software?

No data is stored on your computer. Once data is entered into DataFax, it is sent via the internet to the data server at the Methods Center. Therefore, the amount of space required to download and install the software is minimal. The software itself is approximately 50 – 200 MB.

### 4.6 What if the software file can't be downloaded from the website?

If you can view the website with the file link, but you are unable to download the file, it could be related to a security restriction on your computer. Please contact your institution's Information Technology Department to check for any security restrictions. Alternatively, please contact the Methods Center for further assistance.

### 4.7 What do the different participant colour head icons mean?

A head icon represents a participant binder. The colour of the head indicates the status of the data for that particular participant.

**Green** Head – All CRF pages entered thus far are complete with no outstanding queries.

**Red** Head – At least one CRF page is incomplete or has outstanding queries.

**Empty** Head – A new participant with no data entered thus far.

#### 4.8 What do the coloured icons mean within a participant folder?

A list of CRFs should appear for each participant for each visit. The icon shapes and colours tell you the status of each form. A square shape represents a required form. A circle shape represents an optional form (e.g., event forms).

**Green** – The page is complete and saved as *Final* with no outstanding queries.

**Red** – The page contains missing data, illegal values, queries or other data issues and is saved as *Incomplete*.

**Empty** – A new page with no data entered thus far.

**Lost** – Only the Methods Center can save a page as *Lost*.

#### 4.9 Do I need to complete paper CRFs and upload data to DataFax?

All data must be entered into DataFax. Sites may opt to enter data directly into the database if there is source documentation in medical records to substantiate the data points. Alternatively, data may be collected on paper CRFs and then input into the database. If a site opts to enter data directly into the database, existing paper CRFs must be kept on file (e.g., CRFs completed prior to obtaining access to DataFax). Paper or PDF copies of completed patient questionnaires must also be kept on file.