CHAPTER 18 COMPUTING AND DATA ENTRY

18.1   Computing Systems Overview

Computing for HFM Study can be divided into two broad areas: computing at the Clinical Centers and computing at the Data Coordinating Center (DCC). The purpose of this overview is to describe in general terms how these systems are organized.

Each Clinical Center has a personal computer. These PC's will be used, for study purposes, to run software for communicating over the Internet to the DCC. They may additionally be used for a variety of tasks useful for the centers' work related to the study, such as word processing.

To connect from your PC to the DCC (located in Cleveland, Ohio, at the Cleveland Clinic), you will be making use of the Internet, a world-wide network of computers, composed of and supported by primarily academic, governmental, and non-profit institutions. Using the Internet, you will be able to interact with the DCC's computers in Cleveland.

The PC that sits in your office is not directly connected to the Internet. You must first connect from your PC to a nearby computer that is on the Internet, and then from that computer to the DCC. This nearby computer is called an Internet "node." Just what kind of computer each center will connect to in order to access the Internet will vary from center to center. Some centers will be connected to computers at their institution that are an Internet node. This connection might be through a campus network. Other centers will be utilizing a public provider of Internet access for a small monthly fee. Connecting to such a service will involve making a local phone call to connect using a modem. In either case, this manual will refer to the nearby computer to which the HFM Study center's personal computer connects to gain Internet access as the Local Internet Provider (LIP).

The DCC's computer is also connected to the Internet. Hence, connecting from your personal computer to your LIP allows you to reach the DCC across the Internet. In fact, you'll be using the DCC's computer directly when you enter data, and receive reports and mail messages from the DCC.

18.2   Your HFM Study Personal Computer

Each center is required to have a minimum of one PC dedicated to the purposes of the HFM Study. The DCC's recommended specifications for your PC are as follows:

Monitor

- Color monitor.
  Internet Connection
- A live connection to the Internet.
  Browser Software

Internet Explorer 6.0 or 7.0, Adobe Acrobat Reader, and Oracle Jinitiator 1.3.1.22 for the Oracle 10g application. These can be downloaded from the DCC's website as specified in Appendix A.

18.3   Accessing the DCC Website to Enter Data

See Appendix A for instructions on how to set up your PC to access the DCC's website.

After you have successfully entered the website, you will see a menu titled "HFM Study". At this point, resize the window to the largest that will fit on the screen for optimal viewing. You can then choose a form or report from the menu, or you can go to the "Query" menu to answer or view your queries.

18.4   Passwords

You will have a web username and password and an Oracle database username and password. The usernames should be the same for both: First six letters of your last name followed by the first letter of your first name. There are up to seven letters in a username.   Please do not share passwords. Passwords will need to be changed every 75 days. Passwords are not case sensitive.

18.4.1   Selecting a Good Password

Here are some good references for picking a good password:

- http://www.net.berkeley.edu/dcns/faq/good_pw.html

- http://www.msc.tamu.edu/services/cops/security/goodpasswd.html and

- http://www.cs.umd.edu/faq/Passwords.shtml

Please read them all as they all have good advice.

18.4.2 Changing Your Password

There is a menu option available to change your password.

1. Go into the HFM Study website https://clinicalresearch.ccf.org/fm/ and click on "Logon to the HFMC System"

2. Enter your username and current password then hit enter or click on connect.

3. At the top of the screen, click on "Change your password" and follow the prompts. Be sure to select "MRISP" as the database.

18.5   Instructions: How to Enter Study Data into the Database

Press enter, tab or click your mouse to move from field to field within a form. Note that you will see bubble help when you move your mouse over the top buttons. The upper left button should be the save button. When you are finished entering data for a form, click on the save button, or choose "Save" from the "Action" menu, or press the Ctrl+S (Accept or Commit) function key. The Ctrl+S key corresponds to the Oracle function "Accept" or "Commit". You will see a message at the bottom of the screen indicating how many new records were added to the

database. You can get out of a form by pressing the "Exit" button or choosing "Exit" from the "Action" menu. There is also a speed key for this. If you want to enter another form you should navigate to the top of the form, and press the "Insert Record" button. "Insert" can be selected from the "Record" menu. Unfortunately, you are not permitted to remove records once you have saved/committed them. You will need to send the DCC a query to do that. You are also not permitted to change certain key fields or fields that determine eligibility. Again, you will need to send a query to the DCC.

18.5.1 Keymappings

Ctrl+K means hold down the <Ctrl> key and then simultaneously press the "K" key. Now release "K" and then <Ctrl>. Another way to get to the key mappings is to choose "Keys" from the "Help" menu.

18.5.2 List of Values (LOV)

Note that you may see messages on the bottom of your screen. If you see "List of Values", that means you can choose "Display List" from the "Edit" menu, or press Ctrl+L to retrieve a list of values to your screen which you can scroll through and make a selection.

18.5.3 Editing

If the field is smaller than the text you are typing into it, you can choose "Edit" from the "Edit" menu, or press Ctrl+E when your cursor is in that field. This will open up a pop-up box containing a larger view of that field. Use this also for viewing.

18.5.4 Navigation

Other useful Oracle functions that you can use are "Next Record" and "Previous Record". You can find buttons and speed keys for these and they are also on the "Record" menu. Use these to navigate between forms or detail records (for example, in the medication form).

18.5.5 Error Messages

If you skip over a required field, you will see the error message:

> Field must be entered.

If you enter a value that is not possible for that field, you will see the error message:

> Invalid value for field name.

If you enter a non-numeric character in a numeric field, you will see the error message:

> Legal characters are 0-9 - + E.

If you try to update previously entered data without using the [Change Value] button, you will see:

Field is protected against update.

You will also see other various error messages as well. If you can't figure out why you are getting that particular error message, please write down the complete message, and also choose Help->Display Error while the message is on the screen to see if a further explanation pops up before calling us. If you get stuck, it may help to use Cancel Query or Query->Cancel (if you see "Enter-Query" on the bottom of your screen), Action->Clear All or Record->Clear

18.6   Instructions: How to Change Study Data in the Database

18.6.1 Retrieving Data

Once the data has been entered, you can retrieve it to your screen for viewing:

- Access the form # you want to view.

- Press the [Enter Query] key or button.

Note the hint line will say "Enter-Query".

- Enter the Patient ID, Visit Type and Visit Number.

- Visit number may not be applicable.

- Press the [Execute Query] key or button.

18.6.2   Data Change Within 7 Days

- Retrieve the data.

- Put the cursor on the field that needs to be updated.

- Press the [Change Value] button.

- Change the value by entering the appropriate value

- Press the [Save] button.

- A pop-up box will appear with a Data Change Number.

- Write the Data Change Number on your form next to the question that was changed.

- Press the [OK] button to return to the form.

- No further action is required.

18.6.3 Clinical Center Change to Data After 7 Days

- Retrieve the verified data.

- Position the cursor on the field to be changed.

- Press the [Change Value] button.

- A new screen will appear that will allow you to enter a "New Value" and an explanation.

- Enter the new value in the "New Value" field and text describing the desired change in the "CC Text" field. Please give as much detailed information as possible as to why the value should be updated. The DCC will use this response to investigate the request.

- Press the [Save and Exit] button.

- You will receive an inquiry number after you save the request. Write this number on your form. You can use this number to check to see if the DCC signed off on your inquiry.

- The DCC will take the appropriate action, and then use the DCC Sign-Off screen to indicate the final status of the request.

- A "DCC Sign-Off to CC Initiated Data Inquiry" will be sent to the DCC and CC.

- No further action is required.

18.6.4 Data Change for the Form 100 Series

- Retrieve the data. (Pressing the Execute Query Key)

- Put the cursor on the field that needs to be updated.

- Change the value by entering the appropriate value

- Press the [Save] button.

- No further action is required.

18.7   Instructions: How to Initiate and Respond to Queries

18.7.1 Clinical Center Initiation of Queries

Queries can be initiated by the Clinical Center as described in the above section on changing data.

18.7.2 Clinical Center Response to a DCC Initiated Inquiry

- You will receive a DCC initiated inquiry report through e-mail, or you can go to the "Query" menu and choose "Center Response to DCC Inquiry" to find unanswered queries.

- When the screen appears you can press [Execute Query] to retrieve all unanswered queries, or press [Enter Query] and enter the query # and then press [Execute Query].

- If you do not enter an inquiry number, all unanswered queries will be retrieved. You need to press [Next Record] to navigate to the other queries. Keep pressing [Previous Record] to get back to a previous query.

- Position your cursor on the "DCC text" field".

- Choose Edit->Edit if you want to read the entire explanation from the DCC as to why you are being queried.

- Navigate to "New Value".

- Type a new value for the field being inquired. If a different field requires changing, leave it blank or enter N/A for not applicable.

- Navigate to "CC text", and enter an explanation for your value. This field must be answered in order for the DCC to take action. Please make sure that your explanation is specific and complete.

- The explanation can be up to 2000 characters. Click on the [Save and Exit] button on the bottom of the screen to save the text. Click on [Exit and Don't Save] if you do NOT want to save the text.

- The DCC will then make the appropriate updates to the database.

- It is very important that the CC respond within 3 business days.

18.8   E-mail Alias Lists

From your center's fm-xx study account at the DCC, you will have access to several pre-defined distribution lists. These include:

fm-steeringplus@bio.ri.ccf.org -	Steering Committee plus Committees
fm-steering@bio.ri.ccf.org -	Steering Committee
fm-scoord@bio.ri.ccf.org -	Study Coordinators, plus the DCC
fm-dcc@bio.ri.ccf.org -	DCC personnel

fm-exec@bio.ri.ccf.org -   Executive Committee

18.9   Retrieving Data from Forms

18.9.1 Introduction

Data can be retrieved in several ways from the form application. In order to "query" data available in the database for the information on a given form application, the [Enter Query] and [Execute Query] keys can be used. The screen will be populated with the first set of patient data for the form application being accessed. By pressing the [next record] or [previous record] keys, you will have the ability to view the next or previous set of data.

There are different ways to retrieve data. You can execute simple queries that meet specific criteria, as well as complex queries that satisfy several conditions. The following topics are discussed.

- Matching exact values

- Entering variable conditions

- Matching values that meet a specified pattern

18.9.2 Matching Exact Values

Suppose you want to check on all instances of visits of the 'B' or 'F' type for a given patient ID (040001 for example). The data entry screens can retrieve the record(s) that contains specifically these values. The following are general steps for retrieving records that match exact values:

1. Access the appropriate form via the menu system.

2. Press [Enter Query]

3. Type the values you want to match into the appropriate fields.

4. For this example, cursor to the Patient ID field and type 040001. (The leading '0' must be typed.)

5. Press [Execute Query]

6. Press [Next Record] or [Previous Record] to view the retrieved data.

NOTE: If there is not any data that meets the specified criteria, the following message will be displayed on the status line of your screen:

"FRM-40301: Query caused no records to be retrieved. Re-enter."

18.9.3 Entering Variable Conditions

Sometimes it is not practical to enter the exact values that you want retrieved data to match. For example, you might want to retrieve the following:

- All Form 205's with visit type = "F"

To select data that have a visit type = "F", press [Enter Query] and enter the patient ID number, visit type of "F" and press [Execute Query]. This will bring up all Form 205's with a visit type of 'F' for that participant.

18.9.4 Using Pattern Matching

Pattern matching provides the capability to fetch data where a value for a field fits a certain pattern. This is useful when specifying search criteria on "string" or character value fields.

For instance, suppose you are interested in finding CATAPRES on Form 205:

1. Access the Drug database via the Form 205 data entry screen.

2. Retrieve the medication data for a specific patient.

3. Place your cursor on a blank field in the medication table.

4. Press the [List of Values] key. You will be presented with a blank screen

5. Type CAT or CATAPRES

6. Press the Find key.

7. To select the medication, highlight the medication and double click or highlight and Press the OK key.

18.10 Patient Confidentiality and Data Security

Patient confidentiality of medical records and identity will be maintained at the highest level. All patient data submitted to the DCC will be transmitted as secured encrypted files and reported anonymously with no names, Social Security numbers, etc. It will be emphasized to all staff of the CCs, and any centeral cores, the need for strict confidentiality of all study data, with a specific plan for later data sharing as required by NIH. HIPAA privacy regulations will be followed carefully. All forms, CDs and tapes will be kept in locked cabinets. All computerized files will be protected by means of a password system. All reports prepared by the Data Coordinating Center will be such that no individual patient can be identified. Any publication of trial data will be reported as a group, thus avoiding identification of an individual subject.

18.10.1 System Physical Security

The Server Room in located on campus in the JJNorth Building. Building and department access is limited to authorized Cleveland Clinic and contracted maintenance employees via ID Badge swipe access device at building entrances. The Server room access is restricted to authorized personnel only via ID Badge swipe access device at the server room entrance.

Devices and systems for fire detection are installed and available. Server room undergoes periodic fire marshal inspection by the Department of Safety.

Temperature and humidity are automatically controlled by the heating and air conditioning equipment. Server and battery room temperatures are monitored automatically. Facility Engineering is notified of high temperature alerts for remediation automatically. The System Group are notified at the same time.

A UPS (uninterruptible power supply) is installed, maintained and tested periodically to allow for proper computer equipment shutdown in the case of extended power outages. The UPS automatically sends a page if it goes on.

18.10.2 Storage and Backup

The database is backed up weekly in its entirety using Oracle Recovery Manager hot backups. Then incremental hit backups are done on a daily basis. These are all written to disk where they are in turn copied to tape backup. In addition, transactions between backups are stored in archive logs that are also on hard disk. The tapes are kept in a fireproof safe on site for one month and then moved to Iron Mountain for long-term storage.

18.10.3 Auditing

HFM Study data are contained within an Oracle database. Access is through password protected user accounts. Passwords are forced to be changed at least every 75 days.

All inserted data records are stamped with the date, time and username of the person entering the information.

All changes to data records have a copy of the existing record saved in an audit table and the date, time and username of the person making the change is saved.

All data record deletions have the existing record copied into an audit table along with the date, time and username of the person deleting the record.

Appendix A

HFM Study Website

WEB SITE DOWNLOADABLE UTILITIES

The website https://clinicalresearch.ccf.org/ contains a number of files needed to fully utilize the HFM Study web application.

Included are:

1. Internet Explorer 6.0 or 7.0

2. Adobe Acrobat Reader

3. JVM Sun Software

The following steps must be performed in the order given below:

1. If you do not have Internet Explorer 6.0 or higher already installed, install it by double-clicking on the file.

2. Go to http://www.java.com/en/download/index.jsp. Click on "Free Java Download: and then save it and run it. (There is an instruction link if needed)

Once these components are installed:

Please go to https://clinicalresearch.ccf.org/ and follow the links to HFM Study and then log in.

Appendix B

Key Mapping

FUNCTION	KEY
Block Menu	Ctrl+B
Clear Block	F7
Clear Field	F5
Clear Form	F8
Clear Record	F6
Commit	Ctrl+S
Count Query	F12
Delete Record	Ctrl+↑
Display Error	Shift+Ctrl+E
Down	↓
Duplicate Item	Shift+F5
Duplicate Field	Shift+F6
Edit	Ctrl+E
Enter Query	F11
Execute Query	Ctrl+F11
Exit	Action menu, select Exit
Help	Ctrl+H
Insert Record	Ctrl+↓
List of Values	Ctrl+L
List Tab Pages	F2
Next Block	Shift+PageDown

Next Field	Tab
Next Primary Key	Shift+F7
Next Set of Records	Shift+F8
Previous Block	Shift+PageUp
Previous Field	Shift+Tab
Print	Ctrl+P
Return	Return
Show Keys	Ctrl+K
Up	Up
Update Record	Ctrl+U