

6. Computing and Data Entry

6.1 Computing systems overview

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

Each Clinical Center has at least one 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 Foundation), 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, or it might involve dialing up the institution's computer over a phone line using a modem. 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 FHN 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.

6.2 Your FHN Study personal computer

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

PC specification

A 500 Mhz or better PC is required.

Monitor

Color monitor.

Internet connection

A live connection to the Internet.

Browser software

Netscape Communicator 4.77 or Internet Explorer 5.5 or higher. Adobe Acrobat Reader 4.05. Oracle Jinitiator 1.1.8.14. These can be downloaded from the DCC's website.

Web site downloadable utilities

The website <https://clinapps.bio.ri.ccf.org/download.html> a number of files needed to fully utilize the FHN Consortium web application. Included are: (1) Netscape Communicator version 4.77 cc32d477.exe (2) Adobe Acrobat Reader version 4.05 rs405eng.exe (3) Oracle Jinitiator version 1.1.8.14 jinit11814.exe The following steps must be performed in the order given below: 1) If you do not have Netscape 4.77 already installed, install it by double-clicking on cc32d477.exe This is the latest version in the 4.x series. We've seen numerous problems with the 6.x Netscape and do not recommend it at this time. 2) Double-click jinit11814.exe to install (accept all defaults). This is a thoroughly debugged and Oracle-certified version of Sun Microsystems's Java Plug-In which replaces the browser's built-in Java Virtual Machine when the FHN application is run.

Once these components are installed:

Please go to <https://clinapps.bio.ri.ccf.org/> and follow the links to FHN and then log in to the appropriate database.

NOTE: Using Netscape 6.x and Jinitiator

Aside from other directions in the computing section of the MOP and the above, the user still might not be able to run the application and gets the message to 'Get Plug-In' even after Jinitiator had been installed. The problem is that the plug-in, NPJinit-11814.dll, may not have been copied to the correct directory. It needs to be in the Netscape Plug-Ins directory along with other Java dlls. This seems particularly true for Netscape 6 and higher especially if there is a previous version of Netscape installed. To do to this, use the Windows 'Search' or 'Find' utility (Depends on which version of Windows OS). Once you have located 'NPJinit-11814.dll' copy it to the Plug-Ins directory under the current version of Netscape if it isn't there already.

6.3 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.

The forms were designed assuming a user desktop area setting of 800 x 600.

There is currently a one hour idle time setting in effect. If the one hour idle time is exceeded, the user will see an error message containing the text "ORA-03114". To fix the problem, please log out and then log in again.

After you have successfully entered the website, you will see a menu titled "FHN 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.

6.4 Passwords

You will have an Oracle database username and password. The username is the first six characters of your last name followed by the first character of your first name. Please do not share passwords. Passwords will need to be changed every 75 days. Oracle passwords are NOT case sensitive; i.e., it does not matter if the cap lock is on.

- # Your new password must be at least 6 characters long.
- # Your password must contain at least two alphabetic characters.
- # Your password must contain at least one numeric character.
- # Your password must differ from your old password by at least 3 characters, or not match any of the three past passwords.
- # Your password cannot contain quotation marks OR ANY OTHER SPECIAL CHARACTERS.
- # Your password must begin with a LETTER.
- # Your password should not be a common word, a proper name, or a common phrase.

Selecting a good password

Here are some good references for picking a good password:

http://www.net.berkeley.edu/dcms/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

Changing your password

There is a menu option available to change your password.

6.5 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 F10 (Accept or Commit) function key. The F10 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.

Keymappings

Ctrl+F1 means hold down the <Ctrl> key and then simultaneously press the <F1> key. Now release <F1> and then <Ctrl>. Another way to get to the key mappings is to choose “Keys” from the “Help” menu.

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 F9 to retrieve a list of values to your screen which you can scroll through and make a selection.

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.

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 medication forms).

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 fieldname.

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

6.6 Instructions: How to change study data in the database

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 and visit number. Note that visit number is not applicable for some forms.
- Press the [Execute Query] key or button.

Real-time changes

Clinical Centers can change data within 7 days and the new value is acceptable to the database:

Query the data from the appropriate form.

Position cursor on field to be changed, and then press the [Change Value] button.

Type in the new value.

If multiple fields within the same form need to be changed, repeat the above, starting with positioning your cursor in the new field.

You will receive a data change number for each field that you change.

You will need to save (commit) the data before you leave the form.

If a desired change does not pass an edit check, then none of the changes will be saved if you have made multiple changes. If you quit out of the form at this point the data change numbers will be discarded, but before you quit out of the form, you may be able to change the unacceptable value back to its original state, and then save the form again. Otherwise, you may need to quit out of the form and make the (acceptable) changes again, or make the changes one at a time, saving the form in between each change.

See the section entitled "Data Change Within 7 Days But the Database Will Not Accept It" for how to handle the changes that do not pass the edit checks.

Data change within 7 days but the database will not accept it

Retrieve the data.

Position the cursor on the field where changes were rejected.

Press the [Change Value] button.

Press [Enter] only.

A pop-up box will appear asking if you would like to send a query.

Answer “OK” to the popup box.

A new screen will appear that will allow you to enter a requested value and an explanation.

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

After investigating, 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.

Clinical Center change to data after 7 days

Retrieve the data.

Position the cursor on the field to be changed (only make one change per each inquiry).

Press the [Change Value] button.

A new screen will appear that will allow you to enter a requested value and an explanation.

Enter the new value as well as text describing the desired change. The DCC will use this response to investigate the request.

You will receive an inquiry number after you save the request. You can use this number to check to see if the DCC signed off on your inquiry. (Also document this number on the hard copy of the form).

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.

6.7 Instructions: How to initiate and respond to queries

Clinical Center Initiation of Queries

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

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 Main menu, choose "Forms" → "Inquiry Forms" → "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.

6.8 E-mail alias lists

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

fhn-steering@bio.ri.ccf.org - lists all Steering members

fhn-steeringplus@bio.ri.ccf.org – lists all Steering Committee members plus key others

fhn-dcc@bio.ri.ccf.org - lists all DCC members

fhn-rri@bio.ri.ccf.org – lists those in the RRI Daily Consortium

fhn-ucsf@bio.ri.ccf.org – lists those in the UCSF Daily Consortium

fhn-wake@bio.ri.ccf.org – lists those in the Wake Forest Nocturnal Consortium

fhn-xxx@bio.ri.ccf.org – lists those in Committee XXX

A complete list of these e-mail addresses can be found in the FHN address directory.

6.9 Retrieving data from forms

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] functions can be used. The screen will be populated with the first set of patient data for the form application being accessed. By using the [Next Record] or [Previous Record] functions (record menu or triangular buttons just below the menu), 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

Matching exact values

Suppose you want to check on all instances of visits of the follow-up type for a given patient ID (10001 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) Use the [Enter Query] function.
- 3) Type the values you want to match into the appropriate fields.
For this example, cursor to the Patient ID field and type 10001.

- 4) Use the [Execute Query] function.
- 5) Use [Next Record] or [Previous Record] to view the retrieved data.

NOTE: If no data meet 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."

You must use [Cancel Query] if you decide not to complete the initiated query.

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 203's with visit type = F and visit number >6
- All Form 203's after 12/31/2005

Rather than entering an exact data value, you can enter a relational operator before the data values in one or more fields.

The following table shows some relational operators typically used:

Operator	Meaning	Example
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=	equal to	= '01/01/2006'
!=	not equal to	!=6
>	greater than	>6
>=	greater than or equal to	>=6
<	less than	<6
<=	less than or equal to	<=6

For example, to select data that have a visit number >6, press [Enter Query] and type >6 on visit number field and press [Execute Query]. To select any Form 203's after 12/31/2005, press [Enter Query], type >=01/01/2006, and press [Execute Query].

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.

When specifying a pattern "_" represents any single character and "%" represents any combination of characters. The "_" and "%" symbols are referred to as wild cards.

For instance, suppose you are interested in all patients that have the letter "A" in their Alpha Code.

- 1) Access any data entry screen containing Alpha Code.

- 2) Use the [Enter Query] function.
- 3) Place your cursor on a blank Alpha Code field.
- 4) Type %A% (case sensitive).
- 5) Use the [Execute Query] function.
- 6) Use the [Next Record] and [Previous Record] functions to view the retrieved data.

To further refine the search, to find all patients with an “A” and a “B” (“A” is before “B”, but not necessary beside “A”), restart the process by using [Enter Query], type %A%B in the alpha code field, and then use [Execute Query}.

Count query hits

If you are interested in simply a count of how many records meet your search criteria, use the [Count Query Hits] function in place of the [Execute Query] function. Rather than having a screen full of data returned to your screen, you will receive a message indicating the number of "records" that meet the search criteria. For example, you will see something such as the following:

"FRM-40355: Query will retrieve 3 records"

This function can be helpful if you are interested in determining a count of patients that meets some specific criteria.

Notes:

Queries can be issued in the first block of multi-block forms.