

CHAPTER 6: FORMS COMPLETION, DATA ENTRY AND COMPUTING

6.0 Introduction of data

The Study Coordinator will review all data forms for completeness and accuracy and to ensure timely submission of data to the Data Coordinating Center. Data forms should be filed in an area convenient for study personnel's access. To ensure that the study has quality data, team members must know the purpose of the study, the protocol design, and the sections of the Manual of Operations that are pertinent to their role in the study. If protocol expectations and study goals are clear and common to all team members, then protocol adherence by staff will help ensure quality data collection.

6.1 Form Completion

All study forms should be completed legibly using a blue or black pen. If an error occurs when completing an entry on a form, put an "x" through the incorrect entry and write the correct entry next to it. In the margin, next to the fixed entry, write your initials and the date the change was made. Never, try to place the correct entry over the incorrect entry. Do not transcribe a form from the original completed version onto another form. However, in the rare case that a form gets something like coffee spilled on it and you are worried that you will no longer be able to read some of the values, complete another form, let the coffee spill dry out and staple the coffee stained form to the transcribed form.

Each form has a "**Clinical Center Use Only**" box which is located at the end of every form. This box should only be completed once the form is successfully data entered into the database. If you receive an error message and are unable to commit the form, do not complete any of the information in this box. Once the form is successfully saved, write the username of the person entering the data and the date the form was entered into this box. This information will also be displayed on the database screen.

All data entered into the study database should always match the paper form. Data should be entered within 3 business days from the date the visit was held.

6.1.2 De-Identifying the Participant Consent and Forwarding to the DCC

In order for a participant to be randomized, the DCC will need to receive a de-identified copy of the signature page only of the consent form for the participant to be randomized. We do not need the entire consent; only the signature page. Please make sure that all participant information cannot be seen by DCC staff. This can be best done by using a black marker. The DCC should be able to see the date the participant signed the consent though.

Write the Participant ID and Alphacode in the middle of the page. This way, if it is scanned and emailed to the DCC, we will be able to see it and this information will not be cut off.

It is best if this document is scanned and emailed to pvd-systems@bio.ri.ccf.org. However, if you do need to fax it, please send an email to pvd-systems@bio.ri.ccf.org stating that you are doing this.

6.2 PVDOMICS Study Computing

The PVDOMICS Study Data Coordinating Center's recommended specifications for your PC are as follows:

Internet Explorer 7.0 or higher, Adobe Acrobat Reader, and the Sun JRE download for the Oracle 11g application. These can be downloaded from the DCC's website as specified in **Appendix A**.

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 database website.

<https://qhsapps.ccf.org/forms/frmservlet?config=pvdomics>

After you have successfully entered the website, you will see a menu titled 'PVDOMICS 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 'Inquiry' menu to answer or view your data inquiries.

6.4 Usernames and Passwords

You will have an Oracle database username and password. The usernames are assigned by the DCC's Database Administrators and are usually set up in the following format: 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 are not case sensitive.

Passwords will need to be changed every 75 days. You will be notified via email when your oracle password needs to be changed. If you do not change your password in the allotted time, you will need to send an email message to pvd-systems@bio.ri.ccf.org asking to have your password reset. A new temporary password will be sent to you in a secure e-mail and you will need to retrieve it from the secure site. This temporary password is only valid up until midnight of the same day.

6.4.1 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.

6.4.2 Changing Your Password

There is a menu option available to change your password.

1. Go into the PVDOMICS Study website <http://qhsapps.ccf.org/pvdomics/> and click on 'Logon to the PVDOMICS 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 'RDP10' as the database. Passwords for the PVDOMICS Study will require:
 - 8 or more alphanumeric characters (no spaces or special characters).
 - An alpha character must always appear in the first position of the 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 toolbar 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+K to identify which key is the 'Save' or 'Commit' function key. The Ctrl+S key corresponds to the Oracle function 'Save' or 'Commit'.

Maximize window to see messages at the bottom of the screen. You will see a message 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. 'F4' is the speed key to exit.

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. You are not permitted to remove records once you have saved/committed them. You will need to send the DCC a data change request via the Inquiry System to delete a record (form). You are also not permitted to change certain key fields. (you will need to send a query to the DCC for these key fields).

When entering data, if you receive an error message stating the value is out-of-range, then back out of the form without saving the information and review the data with other staff members and PI if needed. If the value on the paper form is correct, notify the DCC with the information and we can investigate further. It may be that the range needs to be adjusted for that particular field. **Never** enter a value as a placeholder thinking that you will come back and fix the data at a later date.

If a form requires that all fields have a response but your paper version of the form has fields that are blank, **never** enter a value as a placeholder thinking that you will come back and fix the data at a later date. Instead, back out of the form without saving it. Discuss the form with other study personnel and the PI to obtain values for those fields that were missing. In the event that you do not have a value for a required field, contact the DCC for further instructions.

6.5.1 Obtaining the ID and Alphacode for a Participant

When data entering the Initial Enrollment Form for each study, question 1 "Identification Number" will have a list of values key (^), click on the "^". Select the first identification number that is listed. Once you have selected that number, that number will not be displayed the next time an initial enrollment is entered. The Alphacode will be populated once you have successfully committed and saved the

Screening Form. Make sure to write the Identification Number and the Alphacode on the Screening Form. This ID and alphacode will follow the participant throughout the study.

6.5.2 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.

6.5.3 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. You can also click on the 'v' button next to the field to select the response you need.

6.5.4 Editing

If the box for 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.

6.5.5 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).

6.5.6 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 or Item must be formatted as, for example, 90.0 (or some specific format)

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

Field is protected against update.

If you try to enter a Form that has already been entered, you will see the error message:

Error while inserting: ORA-00001: unique constraint (P201194.PVD_XX_PK) violated.

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 contacting the DCC. 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

6.6.1 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 F11 [Enter Query] key, query icon or use the pull down menu option under 'Query'.

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

- Enter the Participant ID.
- Press the Ctrl+F11 [Execute Query] key, execute query icon or use click on the pull down menu option under 'Query' to execute query.

6.6.2 Data Change Within 7 Days

- Retrieve the form you want to view.
- 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 'enter' or [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.
- The database should always match the paper copy of the form you entered.

6.6.3 Clinical Center Change to Data After 7 Days (send 'Data Change Request' to DCC)

- Retrieve the verified data and the form you want to view.
- 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 or 'data change request' 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.
- The database should always match the paper copy of the form you entered.

6.6.4 Data Change for Forms 9 and 10

- Data on Forms 9 and 10 can be changed at any time.
- Retrieve the data and the form you wish to view.
- 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.

6.7 Instructions: How to Initiate and Respond to Data Change Requests/Queries

6.7.1 Clinical Center Initiation of Queries

Queries, or Data Change Requests, can be initiated by the Clinical Center as described in the previous section on changing data.

6.7.2 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 'Inquiries' menu and choose 'Center Response to DCC Inquiry' to find unanswered queries.
- To respond to an inquiry, you **must** use the database Inquiry System. The DCC is unable to accept e-mail responses.
- When the screen appears, press [Execute Query] to retrieve all unanswered queries, or press [Enter Query] and enter the specific query # and then press [Execute Query].
- If you do not enter an inquiry number, all unanswered queries will be retrieved. Press [Next Record] or use the 'up' or 'down' arrow' key to navigate to the other queries. Keep pressing [Previous Record] to get back to a previous query.
- Position the cursor on the 'DCC text' field'.
- Choose Edit->Edit 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 the value. This field must be answered in order for the DCC to take action. Please make sure that the 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 make the appropriate update(s) to the database.
- It is very important that the CC respond within 3 business days.

6.8 Retrieving Data from Forms

6.6.1 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 participant 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

6.6.2 Matching Exact Values

Suppose you want to check on all instances of visits of the 'B' or 'F' type for a given participant ID (110001 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 Participant ID field and type 110001.
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.'

6.6.3 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:

- A specific form with a visit date of 10/20/2016

To select data that have a visit date of 10/20/2016, press [Enter Query] and enter the participant ID number and visit date of 10/20/2016 and press [Execute Query]. This will bring up all of the forms with a visit date of 10/20/2016 for that participant.

6.6.4 Populating WHO Drug Data Fields

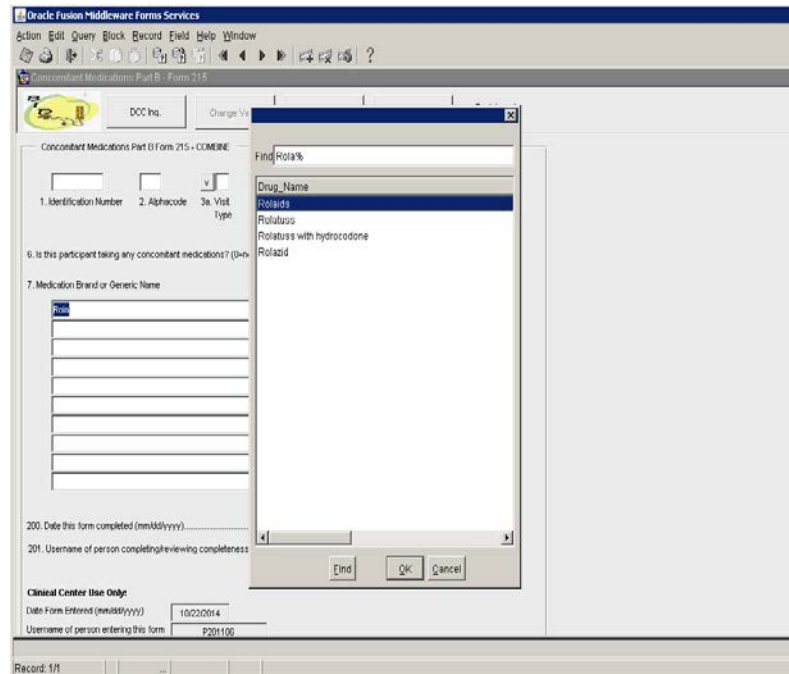
A. The WHO Drug database is used for recording medications on Form 110 Medications. You will need to select the name of the medication from a [List of Values] to populate these forms; you cannot type freehand the name of the medication as there is a chance of misspelling.

For example, a participant is taking a medication, Roloids, on Form 110:

1. Access the Form 110 data entry screen and enter the participant information in Q1 - 3.
2. Database will automatically place the curser into a blank medication field.
3. Obtain the medication name by clicking on the [List of Values] box on the left side of the field and you should get an empty pop-up box. (Alternatively, you can just type in the name of the medication directly into the field.)

The screenshot shows the 'Concomitant Medications Part B Form 215 - COMBINE' window. It has a menu bar (Action, Edit, Query, Block, Record, Field, Help, Window) and a toolbar. The form contains several input fields: '1. Identification Number', '2. Alphacode', '3a. Visit Type', and '3b. Visit Number (Month) (No)'. Below these is a section for '6. Is this participant taking any concomitant medications? (0=no, 1=yes)'. A '7. Medication Brand or Generic Name' section has a list of text boxes. At the bottom, there is a 'Clinical Center Use Only' section with 'Date Form Entered (mm/dd/yyyy)' set to 10/20/2014 and 'Username of person entering this form' set to P201108. A 'Find' dialog box is open over the medication list, with a 'Find' text field and a 'Drug Name' list box. The dialog box has a warning message: 'Warning: Entering % to see all values may take a very long time. Entering criteria that can be used to reduce the list may be significantly faster.' and buttons for 'Find', 'OK', and 'Cancel'.

4. In the 'Find' box, type the first few letters of the medication name 'Rolai' (not case sensitive) and the window will automatically add the % sign. Either hit the 'Enter' key or click on the 'Find' button at the bottom of the window. The window will populate with all medications starting with those 5 letters.



5. Scroll through the list of medications to identify the name of the medication participant is taking.
6. You can further refine this same list of 413 medications by going to the 'Find' line and typing in the additional letters and the window will provide a smaller subset of medications.
7. With the mouse, highlight the medication name and click the 'OK' button. The blank medication field will now be populated with the medication name. Another option is to highlight the medication and double-click. The field will be populated.
8. **Note:** if you determine that the name of the medication is different than what you originally typed, you must click on the 'Cancel' button or the 'X' box and start over.
9. If there are no other medications to be entered, press the "enter" key twice to go to the next question or use the mouse to go to the next question. However, if you press "enter" and type something in the blank row and delete it, you will not be able to exit that row since the computer is expecting you to enter another medication. If there are no other medications to be entered, and the cursor will not go to the next field, select "Record" from the task bar, then select "Remove". You will then be able to use the mouse to get to the next question on the form.

6.9 Participant Confidentiality and Data Security

Participant confidentiality of medical records and identity will be maintained at the highest level. All participant 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 at the clinical center, and any central 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 participant can be identified. Any publication of data will be reported as a group, thus avoiding identification of an individual subject.

6.9.1 System Physical Security

The Server Room is located on the Cleveland Clinic main campus in the JJNorth Building. Building and department access is limited to authorized Cleveland Clinic IT 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 is 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.

6.9.2 Storage and Back-up

The database is backed up weekly in its entirety using Oracle Recovery Manager hot back-ups. Then incremental 'hot' back-ups 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.

6.9.3 Auditing

PVDOMICS 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.

6.10 E-mail Alias Lists

There are several useful e-mail aliases, including:

pvd-systems@bio.ri.ccf.org = DCC Programming Staff

pvd-DCCclin@bio.ri.ccf.org = DCC Clinicians

pvd-steering@bio.ri.ccf.org – Steering Committee

pvd-dcc@bio.ri.ccf.org – QHS DCC Programming and Statistical Staff

Other alias listings can be found in the PVDOMICS Study Address Directory.

Appendix A

PVDOMICS Study - Instructions for Installing/Upgrading Java

Java is the application to run our Oracle Forms application for the PVDOMICS Study. Please follow the steps below to install or update your Java.

Please note that if you don't have permission, you may **need to contact your local IT support**.

A. Go to: <http://www.java.com/en/>

1. Click on the link "Do I have Java?" to obtain your computer's current version number.
2. Click on "Agree and Continue"
3. Click on "Download Java Now" to get current version
4. Click "Agree and Start Free Download"
5. If you get a pop-up box at the bottom of your screen that says "Do you want to run or save JavaSetup.exe from sdlc-esd.sum.com?", then click "Run"
6. On the "Welcome to Java" page click "install"
7. Uncheck the box "Install the Ask Toolbar in Internet Explorer" and click "Next"
8. Java will install
9. Uncheck "Restore Java security prompts" and click "Next"

You have successfully installed Java!

B. Please leave the check mark in "Restart my browser now to complete the installation" and click "Close"

1. Java will close and re-open in another window. Click "Enable" where it says "The Java™ Plug-In SSV Helper add-on from 'Oracle American, Inc.' is ready for use"

C. Go to the computer Start button, left click and select the Control Panel.

1. Select Java and click on the "Security" tab.
2. Click on "Edit Site List"
3. Click "Add" and type the following into the box labeled 'location': <https://ghsapps.ccf.org> and press "OK".
4. Close your browser and restart to access the PVD Database.

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

Appendix C

Instructions for Clearing your IE Cache

If you are unable to see an updated report, try cleaning out your 'cache' in your web browser and then try running the report again.

You can follow these steps:

- a. Open Internet Explorer and then click on Tools.
- b. Then click on Internet options.
- c. Click the General tab, and then, under Browsing history, click Delete.
- d. Here you can select history, cookies, temporary internet files and then click delete.
- e. Refresh screen.

This will clear your Internet Explorer cache.