COMBINE Trial
Data Management System
Users Guide

For Version 1.7 of the COMBINE Trial DMS
(for changes to later versions of the DMS,
see the appropriate DMS Update memos)

September 24, 2003

Prepared by the
COMBINE Coordinating Center
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  OVERVIEW OF DATA COLLECTION</td>
<td>4</td>
</tr>
<tr>
<td>2  DMS FUNCTIONS</td>
<td>6</td>
</tr>
<tr>
<td>3  STARTING THE DMS</td>
<td>9</td>
</tr>
<tr>
<td>4  DATA ENTRY</td>
<td>11</td>
</tr>
<tr>
<td>5  UTILITIES</td>
<td>28</td>
</tr>
<tr>
<td>6  REPORTS</td>
<td>44</td>
</tr>
<tr>
<td>7  REMOTE USER SERVICE (VIA PCANYWHERE)</td>
<td>50</td>
</tr>
<tr>
<td>8  DMS UPDATES</td>
<td>51</td>
</tr>
<tr>
<td>9  APPENDIX A - COMBINE TRIAL DMS QUICK START INSTRUCTIONS</td>
<td>52</td>
</tr>
<tr>
<td>10 APPENDIX B - COMBINE DATA TRANSFER CHECKLIST</td>
<td>55</td>
</tr>
</tbody>
</table>
This Users Guide contains instructions pertinent to the operation of Version 1.7 of the COMBINE Trial Data Management System (DMS). If your DMS has a later version than 1.7, please refer to the DMS update memos and any available addenda to this guide for complete instructions. In the event of significant changes to the DMS, a complete updated Users Guide will accompany the update.

On the Web, the Users Guide and DMS update memos are available at http://www.cscc.unc.edu/combine for viewing or downloading.

- For the Users Guide, go to “Study Documents” on that web page, and then “Procedure Manuals” and then enter the appropriate user name and password. Then, in the list that comes up, find “DMS Manual” and click on “View.”

- For the DMS update memos, go to “Study Documents” on the web page, and then “Memos” and then enter the appropriate user name and password. Then, in the list that comes up, look for entries that begin with “DMS Update 1.1”, “DMS Update 1.2”, etc. The entry for the update memo lists some of the features that came out in the update. For example, the entry for the DMS Update 1.2 memo is

  DMS Update 1.2 (new form version, F2 features for dates and repeating values in CAL and PLC, WOC seq # 02 message)

When you have found the appropriate update memo in the list, click on “View” for that memo.

To save the Users Guide or DMS update memo to your computer so that you can later print it, click on the button on the Adobe toolbar that looks like a floppy disk (see below).

![Adobe toolbar button](image)

Then give the document a file name and choose where you want to save it on your computer.

**IMPORTANT MESSAGE about Computers that have the COMBINE DMS Installed on Them**

**NOTE:** Once the Combine Trial DMS has been installed on a computer, please do not move the system, reconfigure the hardware (e.g. replace the C drive), or upgrade the operating system without contacting the COMBINE Coordinating Center first. Doing so could result in the loss of research data. We have provided a label containing this warning. The label should be placed on any computer running the system.
1 Overview of Data Collection

In the course of performing a study, data for a number of participants must be collected at various times for later analysis. These data items are organized into groups of logically related information called forms or form types. Each form is then assigned a brief mnemonic code for easy reference, i.e. "ADS" for Alcohol Dependence Scale, "DEM" for Demographics form, etc.

It is sometimes necessary to change the content of a form during the course of a study. To allow for such changes, we assign a version letter to each form. The initial version is "A", and subsequent versions follow alphabetically. Thus, "DEMA" refers to "Demographics Form, Version A."

Since each form must be collected one or more times for each study participant, extra information is included to uniquely identify each recorded instance, or record, of a form. These identifiers, or key fields, include Study ID (also known as Subject ID) and Week Number (Week #). The Study ID is a unique code assigned to the participant. The Week # specifies the study protocol week at which the form was collected. If more than one record is collected for a participant at a given Week, a unique Form Sequence number must be assigned to each record.

Data items which appear on a form typically consist of demographic information, questions, and measurements. For simplicity, we refer to all data items as questions and assign a question number to each item. Typical question numbers may include both letters and numbers, e.g. 1, 2, 3a, 3b, etc.

Data items are initially collected on paper forms. Then, the data on the paper forms is entered (or keyed) into an electronic database for statistical analysis.

A database consists of tables of data, arranged into fields and records. Each table (form) can store many records (instances of a form), each containing a set of values for every field (question) in the table.

Each table in the database must have a unique name for identification, as must each field in a table. We assign each table's name to be the form and version of the source of its data. We assign each field’s name to be the name of its table and the question number of the source of its data. Hence, the table containing data for form DEM, version A, is named DEMA and contains fields named DEMA1, DEMA2, DEMA3, etc.

Each record in a table is uniquely identified by its set of key fields. Thus, no two records in a table may have the same set of key field values (Study ID, Form, Week #, Form Seq #).

Finally, each Clinical Center in COMBINE has one primary computer and possibly one or more secondary computers. Data entered on the secondary computers are exported and then transferred to the primary computer. After an export on a secondary computer, the data is removed from it so that the data records are not in two places at the same time (i.e., on both the
primary and a secondary). Likewise, an export is conducted on the primary computer and then the data from it is transferred to the COMBINE Coordinating Center. However, in contrast to a secondary computer, the data on the primary computer is not removed after the export.
2 DMS Functions

The COMBINE Data Management System (DMS) is a set of programs which manage data collected in the COMBINE Clinical Centers. The DMS uses the Visual FoxPro database management system for screen display, data editing, and storage.

The DMS provides several major functions:

♦ Data Entry: Allows data to be keyed, edited and updated.
♦ Data Transfer: Allows data to be sent to the COMBINE Coordinating Center for inclusion in a consolidated database. Also allows data keyed on secondary computers to be moved to the primary computer.
♦ Reports: Provides counts of records entered by form type, export counts, etc.

2.1 User Interface Standards

The DMS uses a combination of menus, function key commands and mouse clicks to control its actions.

2.1.1 Keyboard and Mouse

The DMS uses the keyboard in a conventional way:

The typewriter keys are used to type numbers, letters and symbols.

The cursor control arrow keys highlight menu bar options. Once the cursor is on a menu option, the ENTER key either performs the action or brings up a submenu. The left and right arrow keys move within a field. The down arrow key and TAB move the cursor to the next field. The up arrow key and SHIFT+TAB move the cursor to the previous field. The Home and End keys move to the beginning and end of a field respectively. PAGE UP and PAGE DOWN move to the previous and next screens in a form. CTRL+PAGE UP and CTRL+PAGE DOWN move to the previous and next record.

Pressing ALT moves the cursor to the menu bar. Pressing ALT again or pressing ESC returns the cursor to the data entry window.

Most menu options have shortcut keys which are a combination of the ALT key and a letter, usually the underlined letter. In this guide these are written as ALT+letter, for example ALT+E. To use the shortcut hold down the ALT key and simultaneously press the letter. Specific shortcut keys will be described when the menus are discussed.

Most submenu options (the lists displayed after you choose a menu item) have shortcut keys which are usually a combination of the CTRL key and a letter. To initiate an action with a shortcut key hold down the CTRL key and simultaneously press the letter.
F1 (function key 1) is the help key.

F2 (function key 2) is the field duplication key.

F3 (function key 3) is the list display key.

Menu items can be selected using the mouse. To select an item, move the pointer to the item and press the left mouse button once.

2.1.2 Menus

Most screens in the DMS have horizontal menu bars on the first line. These menus list the options available from the screen. To move the cursor to the menu, tap the ALT key. Once the cursor is on the menu bar, there are two ways to select an option:

- Use the left and right arrow keys to move the highlighted bar to the desired option and press ENTER, or type the underlined letter of the desired option.

- Some menu options have further choices which are displayed in a pull-down list when the option is selected. Use the up and down arrow keys to move the bar to the desired option or type the underlined letter.

Shortcut keys have been defined for some menu and submenu options. To use a shortcut key, press the key combination while the cursor is in the data entry section of the screen. The cursor does not have to be on the menu. Shortcut keys for menu options are ALT and the underlined letter of the options. Most shortcut keys for submenu options are a combination of the CTRL key and a letter. The shortcut keys are displayed on the pulldown lists. Exceptions to these rules are the help key (F1), the field duplication key (F2), the list display key (F3) and the movement keys (PAGE UP, PAGE DOWN, CTRL+PAGE UP, CTRL+PAGE DOWN).

Under some conditions menu options are unavailable. For example if a user does not have delete privileges, the Delete option is not available. Unavailable options are not highlighted and cannot be selected.

2.1.3 Lists

Some fields, for example the Form Name field on the ID screen, can be selected from master lists. When the cursor is in the Form Name field, a list of all available form types can be displayed using F3. Use the arrow, page up and page down keys to move the highlighted bar
through the list. To select an item, place the highlighted bar on the item and press ENTER. The item under the bar will be put in the field.

2.2 Information and Warning Messages

Messages from the DMS are of two types. The first displays a message and tells you to press a key to continue:

```
INVALID: Valid values are: xxxx
Press any key to continue
```

The message remains on screen until you press a key.

The other type of message is used when no user action is required:

```
Login failure. Please retry.
```

It will disappear from the screen after a few seconds. However, you can make it disappear instantly by pressing a key.
3 Starting the DMS

To run the DMS, double-click the ‘COMBINE Main Trial’ icon on the Windows desktop. Note: if your computer has both the Combine Main Trial DMS and the Combine Pilot 3 DMS, do not run both simultaneously. Also, if the computer is the primary computer for the COMBINE Main Trial DMS, the ‘COMBINE Main Trial SECURE_DMS’ disk must be inserted in its drive to run the DMS (this disk is—in most cases in COMBINE—a 250 MB Iomega zip disk). The SECURE_DMS zip disk contains a backup of the COMBINE database on the primary computer. Hence, when you are not using the primary computer, please keep this disk separate from it in case your computer gets stolen.

3.1 Desktop, User IDs, and Passwords

The password screen is the first DMS screen displayed:

At the top of the screen the menu bar lists two options:

(1) Help provides assistance on DMS features.
(2) Quit terminates the DMS.

To use DMS functions you must enter a valid User ID and password at the Login screen. These are assigned using the System Administration utility described later. User IDs are three characters long. Passwords are at least three and at most eight characters long and are not shown on the screen. If you enter an invalid User ID or password, an error message is displayed.

The cursor then returns to the User ID field for re-entry. After 3 failures, the DMS exits automatically.

To exit the DMS from this screen, select Quit from the menu.

3.2 Timeout

If the DMS is started and left unattended, a security problem could occur because an unauthorized person might view confidential data. If a screen saver is installed with password protection using a reasonable timeout setting (under 10 minutes), this potential problem can be avoided.
4 Data Entry

After you enter a valid ID and password, the DMS Main Menu is displayed:

![DMS Main Menu](image)

Select Data Entry to add and modify participant data. Select Utilities to run support programs such as the password program and the export and import programs. Select Reports to display reports such as the Missing Fields Report. Select Help for assistance in using DMS features. Select Version to display the version of the DMS (e.g., Version 1.7). Select Exit to return to the Password screen. Select Quit to close the DMS.

The underlined letters of each option indicate which letter, in combination with the ALT key, comprises the shortcut. The shortcut key for Help is F1.

Press ALT+D to start the Data Entry System.

4.1 ID Screen

The ID screen is the first screen shown:

![ID Screen](image)

Study ID: 
Form Name: 
Version: 
Week #: 
Form Seq #: 01
The data entry mode (e.g. add, change or browse) is determined by which key fields you enter, which records exist in the database, and some form-specific rules.

If you enter all key fields and a record with the specified keys does not exist in the database, the mode is Add. An empty record is displayed for data entry. If you do not have Add privileges and are trying to add a record, you are informed that you cannot add records and are returned to the ID screen.

If you enter all key fields and the specified record does exist in the database, you are notified that the record exists and are asked to choose Change or Browse mode.

If you select Change mode and you have modify privileges, you can change the data or a key field of the record or you can delete the record. If you select Browse mode and you have browse privileges, you can view the record but you cannot change or delete it.

The following table summarizes the mode the data entry system assumes when certain fields are entered on the ID screen:

<table>
<thead>
<tr>
<th>Fields Entered</th>
<th>Found in DB?</th>
<th>Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Fields</td>
<td>No</td>
<td>Add</td>
</tr>
<tr>
<td>All Fields</td>
<td>Yes</td>
<td>Choice of Change or Browse</td>
</tr>
<tr>
<td>Some Fields</td>
<td>Yes</td>
<td>Choice of Change or Browse</td>
</tr>
<tr>
<td>Some Fields</td>
<td>No</td>
<td>Disallowed, return to ID Screen</td>
</tr>
</tbody>
</table>

To summarize, to add a new record for a participant you must complete the Study ID, Form Name, Week #, and Form Sequence # fields. To change records you can enter all or some of the fields on the ID screen.
As you enter the Study ID, it is checked (or edited) by the DMS for validity. If it is not a valid COMBINE ID, an error message is displayed and the cursor remains in the field. If it is valid, the cursor moves to the Form Name field.

The Form Name can be entered in one of two ways. You can type a form abbreviation into the field, in which case the default or current version is automatically chosen and displayed in the Version field. Or you can press the F3 key to display a list of all the forms and form sets in the DMS. Then use the down-arrow key to enter the scrolling list of forms, position the highlighted bar on the desired form, and press ENTER. (Alternatively you can just double-click with your left mouse button on the given form.) The form and version are plugged into their respective fields. Note that this method of using the F3 key is the only way to choose a version other than the default.

Next, the cursor enters the Week # field. Enter the Week # at which the record was collected. Edits check that you have entered a valid Week for the form type.

In COMBINE, by default the Form Sequence # is set to 01. To enter a different Form Sequence # than 01, change that number before you have finished entering all of the other fields on the ID screen.

You can leave the ID screen by one of two methods. If you have entered values for all the fields, the requested record is automatically displayed when the last field is filled. Or you can choose a menu option. The menu options are:

- Help: provide assistance on DMS features
- Inventory: display counts of records in the DMS
- Search: display a record which most closely matches those fields entered
- Exit: leave the ID screen and return to the Main Menu
- Options: brings up a submenu of DMS options you can change
- Quit: leave the DMS.

In the Options submenu, you have the option of turning on and turning off self-administered mode (it is turned on by default).

Self-administered mode is turned on if there is a check mark next to that menu option as in the above picture. Self-administered mode is turned off if there is not a check mark next to the menu option. When a COMBINE participant is entering self-administered forms (usually within a form set), self-administered mode should be turned on so that the participant cannot enter responses using the keyboard, cannot access the Add menu nor use the shortcut keys, and so that the following buttons will appear at the bottom of each screen of the form being entered.
If a self-administered form is being entered in self-administered mode and you need to access the Add menu or use the shortcut keys, enter Alt+F12. If you then later want to disable the Add menu and the shortcut keys, enter Alt+F12 again. Finally, because you cannot view the responses entered on a self-administered form when self-administered mode is turned on, to browse or change such a form, self-administered mode must be turned off.

Finally, you can repeat the last value entered in the ID Screen for Study ID, Form Name, Week #, or Form Sequence # respectively by hitting the F2 key on the keyboard when the cursor is in the given field. That way, for example, if you enter and save one record for a certain Study ID, and then—back at the ID Screen—want to enter another record for that Study ID, you can simply hit F2 in the Study ID field.

4.2 Add / Change Menu

When a record is displayed in Add or Change mode, the top portion of the screen shows the key fields for the record. The cursor is on the first data field of the record. A menu bar fills the first line of the screen. The Add and Change menus are identical with three exceptions: Permanently Missing applies only in Add mode; Delete and Key Field Change apply only in Change mode.

Some options on the menus may not be highlighted. This means that they are not available. For example if you do not have delete privileges, Delete is not highlighted. If you do not have change privileges, Save is not highlighted.

Add Menu:

<table>
<thead>
<tr>
<th>COMBINE</th>
<th>Trial Data Management System - Form Display</th>
</tr>
</thead>
<tbody>
<tr>
<td>Move</td>
<td>Save</td>
</tr>
<tr>
<td>Cancel</td>
<td>Problem</td>
</tr>
<tr>
<td>Help</td>
<td>Display</td>
</tr>
<tr>
<td>Perm.Miss</td>
<td>Delete</td>
</tr>
</tbody>
</table>

Change Menu:

<table>
<thead>
<tr>
<th>COMBINE</th>
<th>Trial Data Management System - Form Display</th>
</tr>
</thead>
<tbody>
<tr>
<td>Move</td>
<td>Save</td>
</tr>
<tr>
<td>Cancel</td>
<td>Problem</td>
</tr>
<tr>
<td>Help</td>
<td>Display</td>
</tr>
<tr>
<td>KFChg</td>
<td>Delete</td>
</tr>
</tbody>
</table>

4.3 Field, Screen, and Form Movement

In Add mode you will usually enter fields in sequence. However in both Change and Add modes you can move through fields, screens, and records using the menus or shortcut keys. The Move option of the menu bar lists the available options:
Next Field             TAB, Down Arrow  
Prev Field             SHIFT+TAB, Up Arrow  
Next Screen            PGDN  
Prev Screen            PGUP  
Next Form              CTRL+PGDN  
Prev Form              CTRL+PGUP  
Next Line              CTRL+RIGHTARROW  
Prev Line              CTRL+LEFTARROW  
Jump to Field          CTRL+J  
Switch Paths           CTRL+W  

Most of the options are self-explanatory. TAB (and Down Arrow) and SHIFT+TAB (and Up Arrow) move to the next and previous field respectively. PAGE DOWN and PAGE UP move to the next and previous screen of a form. CTRL+PAGE DOWN and CTRL+PAGE UP move to the next and previous records in the current search order (this is described in more detail below). If you go past the last record in the current search order, the first record will be shown again, or if you go past the first record in the current search order (using the Prev Form menu option or CTRL+PAGE UP), the last record will be shown again. CTRL+RIGHTARROW and CTRL+LEFTARROW move to the next and previous line of a multi-line form. If the form is not a multi-line form these options are dimmed. COMBINE has no multi-line forms.

Jump to Field allows you to move to a specific question on the form. Selecting this option brings up a window in which you enter the number of the question to which you want to go:

If you enter an invalid number the message 'Field not found' will be displayed in the window.

Enter another field or press ESC to return to the data screen.
Jump to Field allows you to go to skipped fields, permitting you to view screens which may have been skipped entirely. However you cannot enter values in these skipped fields. Jump to field will not let you bypass a must enter (mandatory) field. If you enter a question number which falls after a must enter field which is blank, the cursor instead stops at the must enter field.

Switch paths allows you to control the order in which records are presented when you select Next Form and Prev Form. The default order is by ID. In that case, “Searching by ID” is displayed at the bottom left of the grey bar that contains the record’s key fields and that is above the record (see the above picture). With this path, you can cycle through all of the records for a given Study ID. Hence, the next record for the current Study ID is shown when you select Next Form (within the given Study ID, the records are sorted first by Form Name, then by Week #, and then by Form Sequence #). In Form order, “Searching by FORM” is displayed in the grey bar above the record. Using form order, you can cycle through all of the records for a given form (e.g., all DEM records). Hence, the next record for the current Form is shown when you select Next Form (within the given Form, the records are sorted first by Study ID, then by Week #, and then by Form Sequence #).

Selecting Switch Paths toggles the path between Searching by ID and Searching by Form.

4.4 Edits (and Problem Menu)

Each data field that you enter has an associated trio of status bytes which stores additional information about the field, such as whether the field is empty, missing, or contains an out-of-range value. The Problem option on the Add and Change menus gives you a way to provide this additional information.

The status bytes for a field are displayed in the bottom right of the grey bar above the record (they are called the “Field Status” there—see the previous picture). COMBINE does not use the middle status byte and so it is always ‘E’ in COMBINE. Also, the first status byte of a field is displayed as a light-grey letter after the given field. For example, in the following,

| A. Patient Initials: | RGH A |

the light-grey 'A' after the field is its first status-byte and it indicates that the entered value was accepted by the DMS. Another example is that a light-grey 'E' appears after the field if the field is empty.

As you enter data values into a record, they are edited. If you do not have modify privileges, you will be alerted:

YOU ARE NOT AUTHORIZED TO MODIFY RECORDS

Press any key to continue....
and the field’s prior value (blank or otherwise) is restored.

If a value fails an edit, for example it is out of range or inconsistent with other values, an error message alerts you and gives the valid range:

```
INVALID: Valid values are: xxxx
Press any key to continue....
```

Press any key to clear the error message and return to the field (you will notice that a 'D' for Dirty is made the first status byte of the field). If you made a keying mistake, retype the value. However, if the value is correct you must confirm it. Use the Problem menu to do this:

Choose **Confirm field** to confirm that an out-of-range value is accurate by setting the first status byte to 'C'.

Use **Unresolvable field** when a value cannot be collected or when the value you did collect is suspicious and should not be used in analysis. **Unresolvable field** sets the first status byte to 'U' and, if the field is blank, fills the field with equal signs (==). Note that you can set a field to Unresolvable by keying the equal signs into the field rather than using the Problem menu.

**Set Rest of form to Unresolvable** fills all remaining fields on a form with equal signs and sets their first status byte to 'U'.

**Reset field to blank** removes the value in the field and sets the first status byte back to 'E' (empty).
Note log and Questionable log allow you to attach a comment to a field. Choosing either option opens a window in which you can type comments.

If a note log or questionable log has already been entered for the field, it is shown in the window and you may edit the existing text. The window is empty if no log exists for the field.

There are some options on the menu bar. Choose Delete to delete the log displayed. To leave the log window without saving changes, select Cancel. Choose Save to save changes and return to the record.¹ To print the log, choose Print. (Note: the Print option currently may not work on some of your COMBINE computers.)

Note logs and questionable logs function similarly but are used in different contexts.

Use a note log to comment on a value, for example, to explain an 'other' response.

Use a questionable log to mark a field which may be incorrectly recorded on the form and needs review. Questionable logs will not be often used in COMBINE.

Adding a note or questionable log sets the third status byte to N for Note logs, Q for questionable logs, or B for both.

The final option in the Problem menu is the Checked data query option. To make it easier for the COMBINE Coordinating Center to resolve data queries sent to your clinical center, please use the Checked data query option to mark a given data field as having been checked and

¹ After you have finished changing or adding the given record, please note that you need to save that record (see Section 4.12) to save, not only your data changes or additions, but also any note log or questionable log changes or additions that you have made.
confirmed in response to a Coordinating Center query. Here, the option marks the field by assigning an 'H' to its first status byte.

4.5 Skips

Some fields are answered conditionally. That is, a certain response to one field can cause subsequent fields to be unnecessary or irrelevant. In the DMS these fields are skipped. After a response is entered into the trigger field, the cursor skips ahead to the next relevant field. This field might be on the same screen or several screens ahead.

You cannot move to a skipped field using the Next Field or Prev Field keys. The only way to move to a skipped field is by using the Jump to Field option on the Move submenu. Once the cursor is positioned on a skipped field, you cannot enter a value into the field.

The first status byte of a skipped field is changed to indicate the field is skipped. The first status byte’s value remains the same but is changed from upper to lower case.

4.6 Inventory Display

The DMS maintains an inventory of records entered for each participant. It can be displayed from the ID screen or when a data entry record is on the screen.

From the ID screen, to show the inventory choose Inventory from the menu (ALT+I).

If you have entered a Study ID, the inventory for that participant is shown. If you have not entered a Study ID, an inventory of the entire database is shown.

To show the Inventory for the current participant from a data screen, choose Display from the menu and, from the submenu, select Inventory. (Alternatively, you can use the shortcut key CTRL+I.)

The Inventory Display lists the number of records entered for each form type in the database. Where applicable, a count of unverified records for the form type is also displayed (this count is not applicable to any forms in COMBINE).
4.7 Viewing Entry and Modification Information for a Record

If you are viewing a record in Change or Browse mode, you can view entry and modification information for the record by selecting Entry Info under the Display menu (see the above menu).

After you do that, a dialog box like the following comes up.

![Entry Information Dialog Box]

The dialog box indicates the date and the COMBINE computer that the record was entered on. Furthermore, if the record has been modified since it was entered (either data were changed or a key field was changed), the date and the COMBINE computer on which the record was last modified is displayed. Otherwise, the dialog box indicates that the record has not been modified since it was entered. Finally, as mentioned in the dialog box, please note that the accuracy of the dates displayed depends on the given computer date being accurate when the record was entered or modified.

4.8 Permanently Missing Forms

If you are unable to collect an entire record of required data for a participant, enter the record into the DMS and set it to permanently missing. This tells the Coordinating Center staff that you will never be able to get the information so they will not ask you about it.

A record can be set to permanently missing only in Add mode. To set a record to permanently missing, choose Perm. Miss. from the Add menu. You are prompted to confirm that the record is permanently missing:
If you have already entered data into some fields and then decide to set the record to permanently missing, the fields will be blanked. You are prompted to confirm again:

![Confirm Permanently Missing - Form Contains Data]

When a record is set to permanently missing, the first status bytes for all fields are set to 'P'. When a permanently missing record is displayed, a message in the grey bar above the record informs you that the record is permanently missing. You cannot add data to any field of the record.

### 4.9 Delete

To delete a record, select Delete from the Change Menu. You will be prompted to confirm the delete:

![Delete Confirmation:]

Press 'Yes' to delete the record or 'No' to return to the screen. After you delete a record, the ID screen is redisplayed.

If you do not have delete privileges, or if you are in Browse mode instead of Change, the Delete option on the menu will not be highlighted. Delete privileges are granted via the System Administrator utility.

### 4.10 Key Field Change

When a record is displayed for modification, most fields can be changed by simply entering a new value. However to change the key fields, the fields which identify the record, you must use KFChg. from the menu. With this option you can change the Study ID, the Week # and the Form Sequence #.

A screen similar to the ID screen will be shown:
Type in a new value for the field(s) you want to change.

If there is a record with the new key field values in the database, the key field change is not accepted. When you are satisfied with the new values, go to the menu and select Save. To cancel the change, go to the menu and select Cancel.

The window will close and the record, with the new key fields, will be displayed. The Delete option is no longer highlighted. Deletes are not permitted after a key field change.

**NOTE:** If you choose Cancel from the Change menu, the key field changes will be lost. This means you must save the data record (see Section 4.12) to save the key field changes as well as any data changes.

If you do not have Change privileges, KFChg. on the Change menu will not be highlighted.

### 4.11 Help

Help is an option on most of the primary menus in the DMS. It can be selected from the menu or by pressing F1. Help provides you with assistance on using the DMS features.

### 4.12 Save and Cancel

When you are in Add mode, a record is *automatically* saved when you:
enter the last field on a record; or
use CTRL+PAGE UP or CTRL+PAGE DOWN to go to another record.

In the second case you are prompted:

When you are in Change mode, a record is automatically saved when you:

change the last field on a record; or
use CTRL+PAGE UP or CTRL+PAGE DOWN to go to another record.

In the second case you are prompted:

You can also save a record manually by selecting Save from the Add or Change menu.
There are some situations in which you must manually save a record:

a) When you are in Add or Change mode and the response to a trigger field causes all remaining fields on a record to be skipped, you get the message:

“Press Alt+S to SAVE this form.”

b) If you are in Add or Change mode and must use an option from the Problem menu (such as Confirm field or Unresolvable field) on the last field of a record, you get the message:

“This is the last screen of the form.”
c) If you are in Change mode and want to return to the ID screen. (Again, the record is automatically saved though if you change the last field.)

In any of these cases, select Save to save the record and return to the ID screen.

Save is not available when you are in Browse mode. See Section 4.1 for a description of Browse mode.

If you have entered incorrect information and want to cancel all changes, choose Cancel from the menu. You will be prompted to confirm:

![Confirmation of Cancel]

If you select ‘Yes’ the ID screen will be displayed.

### 4.13 Form Set Mode

Form sets are groups of forms which are displayed one after another automatically. When the user completes one form in the form set the system automatically saves that form and displays the next form in the set without returning to the ID screen.

In COMBINE, form sets have been created for each week of the study to facilitate administration of participant-entered forms. For example form set W0A is the first form set used at Week 0; W0B is the second form set used at Week 0; W01 is the form set used at Week 1.

To choose a form set from the ID screen, enter the form set mnemonic into the Form Name field. Alternatively, you can select the form set from the drop down form list (which is displayed by pressing F3 when the cursor is in the Form Name field). After you have finished entering the values for the fields in the ID screen, the first form of the form set will be displayed.

In COMBINE, all forms in form sets are self-administered forms. If self-administered mode is turned on as it should be when a COMBINE participant is entering a form set in the DMS, the Add menu at the top of the screen is hidden (self-administered mode is turned on by default). The user is only allowed to respond to questions so there are no menu options. To bring up the hidden Add menu when options are needed press ALT+F12. (See Section 4.1 for more information on self-administered mode and self-administered forms.)

If you must interrupt a participant entering a form set in-progress, it is best to have him or her finish the current form. Then press ALT+F12 to display the menu and choose Cancel. When the participant resumes entering the form set, the first form in the form set which has not been
entered (the one you canceled) is displayed. If the participant has only completed a few questions on the current form, you might choose to Cancel this form which will cause those questions to be repeated when the participant resumes entering the form set.

To resume a form set, go to the ID screen and enter the same information you used to start the form set (i.e. Study ID #, Formset, Week #, Form Sequence #) and the computer will automatically display the first form that you canceled.

If you are keying from paper those forms which are set up to be self-administered, it is a good idea to turn off ‘self-administered’ mode. By doing so the menu bar will be displayed in Add mode and you will be allowed to use the keyboard to enter values.

To turn off self-administered mode, on the ID screen, choose Options. The single option is ‘Self Administered’. Click on the option to toggle it off which will make the check mark next to the option go away. (Self-administered mode is turned on by default so the next time you start up the DMS, it will be turned on again.)

4.14 Backing up the Database when Quitting the DMS (or when doing an Export etc.)

To close the COMBINE Trial DMS, select ‘Quit’ from either the Main Menu or the menu on the ID Screen (see pictures of these menus at the beginning of Chapter 4).

If you have entered, changed, or deleted data in the database, a complete backup of the database will then be conducted. A backup of the database is also conducted when you do an export (see Sections 5.2 and 5.4) or if you select ‘Backup DMS to diskette’ from the Utilities menu (see Section 5.5).

Locations of Backups of the DMS
On the primary computer, the database is backed up to (1) the disk labelled “COMBINE Main Trial SECURE_DMS” (which is—in most cases in COMBINE—a 250 MB Iomega zip disk) and to (2) one or more 3½ inch “Backup diskettes.” On a secondary computer, the database is backed up to (1) a folder on the C drive and to (2) a 3½ inch “Backup diskette.”

The 3½ inch backup diskette should be labelled with the COMBINE Computer # of the computer whose database it is a backup of (e.g., “TX00” for the primary machine at clinical center TX; “TX01” for secondary computer TX01, etc.). NOTE: each backup diskette should only be used to back up the computer it was created for, which should be the same as the COMBINE Computer # on its label. You should not use the same backup diskette on more than one computer because, if you do, it will only contain a backup of the last computer you used it on. Finally, each secondary computer will likely require only one backup diskette. However, the primary computer may require more than one backup diskette if enough data has been entered on it. In that case, each of these backup diskettes should be labelled with, not only the appropriate COMBINE Computer #, but also the sequence # of that diskette: for example, “Backup Diskette #1,” “Backup Diskette #2,” “Backup Diskette #3,” etc.. More information about these additional backup diskettes is in the “Backing up the DMS” section below.
The backup diskette(s) for a given computer are reused on that computer each time a backup is performed. The same applies to the SECURE_DMS zip disk for the primary computer.

**Backing up the DMS**

Please read the “Locations of Backups of the DMS” section above before reading this section.

Again, a complete backup of the data in the computer’s DMS is carried out when you “Quit” the DMS after entering data, when you do an export, or when you select “Backup DMS to diskette” from the Utilities menu. On the primary computer, the data is first backed up to the SECURE_DMS zip disk. On a secondary computer, the data is first backed up to a folder on the C drive.

Then, on both primary and secondary computers, the following dialog box is displayed.

Accordingly, please insert the first backup diskette for that computer (which may be the only backup diskette for it) and click “OK.” A status window is then displayed for you to monitor the progress of the backup.

If the backup requires more than one diskette, you will then be asked to insert “Backup diskette number 2,” “Backup diskette number 3,” etc.. Please insert the appropriate diskette each time. **Note:** if it is the first time that you’ve been asked to insert Backup diskette #2, Backup diskette #3, etc. (or if you have lost one of these diskettes), please insert a blank, formatted, 3½ inch high-density diskette and the DMS will be backed up to it.¹ Then, please be sure to **label** the new diskette with the appropriate backup diskette number (e.g., “Backup Diskette #2”) **AND** the appropriate COMBINE Computer # (e.g., “TX00”).

**Making a new Backup diskette #1**

If “Backup diskette #1” for a computer becomes lost or damaged, the way to create a new one is to use the “Backup DMS to diskette” option from the Utilities menu (which is on the Main Menu). Here, please insert a blank, formatted, 3½ inch high-density diskette when the dialog box with the prompt, “Please insert Backup diskette number 1 in drive A,” is displayed.¹ Then, after creating the new backup diskette, please remember to **label it** with the correct COMBINE Computer #.

¹If the diskette is not blank, you will get the message “This diskette is not empty. Choose 'OK' to continue, CANCEL to insert another.” If you then click “OK,” any existing files on the diskette will be deleted before the DMS is backed up to it.
4.15 Some COMBINE Form-specific Features

**F2 key to repeat data values or increment dates – CALA, TLFA, PLCA forms**

Sometimes on a form you have fields that are the same kind: for example, in the TLFA form, you have the “# of Standard Drinks” for Day 1, Day 2, … . To make data entry easier, in some of these cases, you can hit the F2 key on the keyboard to repeat in one of these fields the last value entered for a field of the same kind. For example, if you entered 00.0 drinks for the Day 1 field in TLFA, and the COMBINE participant also had 00.0 drinks for Day 2 and Day 3, you can hit F2 in the Day 2 and then the Day 3 fields to enter 00.0 in those fields as well. Besides the Day 1, Day 2, … fields in the TLFA form, this feature is also available in the same way in the CALA form across Day 1, Day 2, … for the fields SECs, Dr. Code, and Soc. Code respectively. Likewise, it is available in the same way in the PLCA form for the NALT: PP fields (questions 1b, 2b, ..., 10b) and for the ACAM: PP fields (questions 1c, 2c, ..., 10c).

This F2 key can also be used on some date fields of the CALA and PLCA forms to increment in one of these fields the date by one day compared to the last-entered date in a field of the same kind. For example, if you enter 06/27/03 for the date for Day 1 in CALA, for example, and then hit F2 for the date for Day 2, it will enter 06/28/03 in that field. Likewise, if you then hit F2 for the date for Day 3, it will enter 06/29/03 in that field. Besides the Date fields across Day 1, Day 2, … in CALA, this feature is also available in the date fields that correspond to questions 1a, 2a, …, 10a in the PLCA form.

**Notelogs automatically coming up – AEDA, AEDB, FEDA, FEDB forms**

First, please note that, in the AEDB and FEDB paper forms, the “OTHER DRUG USE” fields (# 37, 38, …, 47 in AEDB and # 36, 37, …, 46 in FEDB) have a place where one can “Specify” what specific drug is/was being taken. Also, please recall that to enter this specific drug in the DMS, one should enter for the given field (e.g., “42. Amphetamines” in AEDB) a notelog that contains the name of the drug (e.g., “speed”). Anyway, to facilitate specifying the drugs in this manner in the DMS, a notelog automatically comes up for the above fields in AEDB and FEDB if one enters a response of “Yes” to, for example, “42. Amphetamines” in AEDB. Finally, this functionality is also present for the analogous fields in the AEDA and FEDA forms.

---

2 It should be stressed that the F2 key to repeat a value or increment a date is most useful if the given form is filled out from the beginning of the form to the end. This is because, as mentioned, the F2 key repeats the value (or increments the date) that was last-entered for a field of that kind. Hence, in TLFA, for example, if you enter 01.0 drinks for Day 1, skip down to Day 5 and enter 03.0 drinks, and then hit F2 in the Day 2 field, the value that will be entered for Day 2 is 03.0 drinks since that value was the last one entered.
5 Utilities

The utilities are programs which are separate from the data entry functions of the DMS but which affect how it runs. The utilities are run by selecting Utilities from the main menu. A submenu lists the available options (see example below).

5.1 System Administration

To use the DMS you must log in using a User ID and password. You use the password utility to assign User IDs, passwords, and privileges to users. Generally this system administration task is assigned to a single person called the data coordinator, or to the overall project coordinator for a site. Each user should be assigned an individual User ID and password and should always use this ID in the DMS. Users should be given access to only those tasks appropriate for their training and level of responsibility within the organizational structure of a clinical site. For instance, it may be appropriate to give the P.I. privileges to “browse” records, but not to “add”, “change”, or “delete” records. Whereas, a data entry specialist would need to have at least “add” and “change” privileges within the system.

To run the password utility, choose Sys Admin from the Utilities submenu.

Another submenu is then shown giving four choices:
To add new user IDs and passwords, choose Add User:

Enter the user's login ID and password. Enter the password again for verification. Choose which privileges the user is allowed.

Click on an option to select it. A checkmark in a box grants the associated privilege.

From the Sys Admin Utility you can also ‘Set Privileges’ to change what a user is allowed to do in the DMS; remove users from the system with ‘Delete User’; and change a user’s password with ‘Change Passwords’.

Only a user with data coordinator privileges can add users or modify privileges. Individual users can change their passwords.

The DMS is shipped with a default Data Coordinator ID and password. Please add your own data coordinator ID by creating a new ID and assigning that ID data coordinator privileges.
5.2 Secondary PC to Primary PC Export

Periodically data entered on the Clinical Center secondary computers will be taken from the secondary PCs (Exported) and moved to the primary PC (Imported). The export process involves several steps:

1. A complete backup of the data on the secondary PC is made to diskette.
2. The data on the secondary PC is put on a data transfer diskette.
3. All data is removed from the secondary PC.

To start the export process, choose “Export Files” from the Utilities menu (a picture of this menu is in Section 5.1). The data in the DMS will then be backed up to a folder on the C drive and then to the 3½" backup diskette for that secondary computer. **Note:** Please read Section 4.14 “Backing up the Database when Quitting the DMS (or when doing an Export etc.)” for a description of this backup process. Finally, please note that the database **must** be backed up to the backup diskette, or the export will be aborted.

After the backup has finished, a dialog box like the following comes up.

![Dialog box](image)

Here, please insert a blank, formatted, 3½ inch high-density diskette into drive A. Click “OK” when the diskette is in the drive. Also, note that the above dialog box tells you what the name of this data transfer diskette will be (or, more specifically, the transfer file that will be put on it). Using the name “CBMTX01022” in the above figure as an example, “CBM” stands for “COMBINE Main Trial,” “TX01” indicates that the export is from computer TX01, and “022” is the export sequence number. The first export from a given computer has sequence # 00, the next has sequence # 01, and so forth.

Then the DMS proceeds to export the data and a “COMBINE Trial DMS - Export Summary Report” is displayed. **Note:** please do not remove the transfer diskette from the computer when the report is displayed—instead, please leave it in the A drive until indicated below. Also, please see the introduction to Chapter 6, “Reports,” for the functionality of the buttons on the report’s “Print Preview” toolbar.
The top of the export summary report contains the transfer diskette name and the date of the export. Then, the forms in the DMS are listed in alphabetical order and the number of records exported for each form in the following categories—“Add,” “Change,” and “KF Change” (Key field change)—are listed. A given record can only be in one category, which is determined by the last action done on the record. A record is counted as an “Add” if it was simply entered into the database; as a “Change” if the data in it was later changed; and as a “KF Change” if a key field change (see Section 4.10) was later done on the record (if data and key fields of the record were changed during the last time the record was saved, the record is counted as a KF Change). Finally, the right-most column consists of the total number of records exported for the given form, and cumulative totals across all of the forms for each of the four columns are at the bottom of the report. Also, please note that the number of deleted records for a form is not listed in the report because they are not “exported” from a secondary computer—instead, at the time of the deletion they are immediately removed from the database.

If you wish to send the report to the default printer for the computer, please click the button with the printer icon on it on the report’s toolbar. Printing the report also closes it. Do not try to print the report if the computer is not connected to a local or network printer. Finally, if you wish to close the report without printing it, click on the X in the upper right corner of the report window.
After you have printed or closed the report, the export files are compressed into a single file which is copied onto the data transfer diskette. Then all of the data is removed from the computer’s database.

Next, a message is displayed that says something like “Please Label This Transfer diskette Number CBMTX01022. Press any key to continue….” You can then take out the data transfer diskette (either when this message is displayed or after you press any key to continue).

Please label the transfer diskette using the labels supplied by the Coordinating Center. These labels look like this:

```
COMBINE TRANSFER DISKETTE

Computer #:
Transfer # & Date:
Transfer # & Date:
Transfer # & Date:
Transfer # & Date:
```

Because you will put the COMBINE Computer # on the label, there is no need to put the full transfer file name “CBMTX01022” on there. Instead you can just put the export sequence number “022”, for example, for the Transfer #.

Once labelled, please give the data transfer diskette to the data coordinator at the Clinical Center who is in charge of the primary computer. He or she will then import the data into the primary computer.

**Note:** If you get a fatal error during an export, restart the export process using the same backup diskette and a new blank transfer diskette. Please contact the Coordinating Center if you continue to have problems or have any questions.

Finally, please note that backup copies of the files on the data transfer diskette are kept on both the secondary computer and—after the data is imported into it—on the primary computer as well. Thus, the diskettes do not need to be stored for archival purposes. Accordingly, after the data has been successfully imported onto the primary PC, you can reuse this data transfer diskette for another export on the given secondary PC after first deleting the old files on the diskette.

### 5.3 Import into Primary PC and Handling Rejected Records

COMBINE study data keyed on secondary PCs are transferred to the primary computer on 3½" diskettes. At the Clinical Center, the data on these diskettes must be **imported** into the primary computer’s database using the import facility of the DMS.
Import Process

To start the import process, choose “Import Data” from the Utilities menu (a picture of this menu is in Section 5.1). The following dialog box will then come up.

Accordingly, please insert the data transfer diskette from the secondary computer into drive A and click OK. The DMS then checks to see if you inserted a valid transfer diskette.

Also, please note that the transfer diskettes from each secondary computer must be imported in sequential order. For example, with respect to the transfer diskettes from computer TX01, CBMTX01000 must be imported first, then CBMTX01001, then CBMTX01002, and so forth (see Section 5.2 for the naming convention of the diskettes). If a diskette from a given secondary PC is processed out-of-order then, the DMS will display a dialog box like the following.

Also, in the lower right corner of the screen will be a blue window like the following.

If the unusual sequence of diskettes is OK (i.e., it was expected by you), select “Yes” on the above dialog box. Otherwise, select “No” and consult with the Coordinating Center before processing more diskettes from this secondary computer.
However, if a valid transfer diskette has been inserted and is sequentially in order (or, if it was not in order, the unexpected sequence was OK and so you chose to continue importing the diskette), the import facility begins importing the records on the transfer diskette. For each record on the diskette it checks to see if there is already a record in the primary computer’s database that has the same values for the key fields Study ID, Form Name, Week #, and Form Seq # (e.g., TX0034332, OCD, 00, and 01 respectively). If there is already a record in the primary database with the same values for these key fields, the record on the diskette is rejected—that is, it is not added to the primary database. It is rejected because there should not be more than one record with the same values for these key fields. However, if there is not already a record in the primary database with the same values for these key fields, the record on the diskette is accepted—that is, it is added to the primary database. Finally, please note that the record’s Version is irrelevant here; if both the record on the diskette and one in the primary database have the same values for the above four key fields but have different versions, the record on the diskette is still rejected.

After the records from the data transfer diskette have been imported, the “COMBINE Trial DMS - Import Summary Report” is displayed. (Please see the introduction to Chapter 6, “Reports,” for the functionality of the buttons on the report’s “Print Preview” toolbar.)

The top of the import summary report contains the transfer diskette name and the date of the import. Then, the forms in the DMS are listed in alphabetical order and the number of records
accepted and rejected for each form in the categories “Add,” “Change,” and “KF Change” (Key field change) are listed. Please see section 5.2 for an explanation of how a document is determined to be in a given category. On the right side of the report, there are subtotals of the number of accepted and rejected records for each form as well as a combined total for each form. Finally, at the bottom of the form are cumulative totals across all of the forms for the various columns.

Click the print button on the report’s toolbar to print and close the report. (Do not try to print the report if the computer is not connected to a local or network printer.) Click the X in the upper right corner of the report window to close the report without printing it.

Then, if there are no rejected records, the following dialog box comes up.

![Import complete.
Process another data transfer diskette?](image)

Click “Yes” if you want to import data from another data transfer diskette and “No” if you do not.

The next section describes what happens after you print or close the report if there are rejected records.

Rejected Records Processing
Compared to earlier versions of the COMBINE DMS, an easier way to handle rejected records has been introduced in Version 1.7 of the DMS. The principal goal here is to allow the user to examine both the rejected record on the data transfer diskette from the secondary PC AND the corresponding record already in the primary computer’s database (1) to determine why the given record was rejected and (2) to take the appropriate action. The way the user can examine both records in these versions of the COMBINE DMS is to “import” the rejected records into a secondary computer. Details of how to create a new diskette that contains these rejected records so that they can be imported into a secondary computer follow. Then, in the next section, the import of these rejected records into the secondary computer is described. Finally, in the last section, the reasons why a record may be rejected and the appropriate action to take after the rejected record has been imported into the secondary computer are discussed.

Let us assume then that the import summary report above indicated that there were rejected records. Then, after you have printed or closed that report, another report called the “COMBINE DUPLICATE RECORD LOG” is displayed that lists those rejected records.
At the top of this report is the name of the data transfer file that the rejected records were on and the date and time that the given import took place. Then the body of the report contains the list of rejected records. Here, the rejected records are grouped according to form, and the study id, form, week, form seq #, entry PC, and entry date of each rejected record is listed, where the entry date is the date the rejected record was entered in the entry PC’s database as opposed to the date, if any, that it was last modified. Finally, if there are many rejected records, don’t forget to use the scroll bar to scroll down the report or to use the “Next Page” button on the report’s toolbar.

Then, after this report has been printed or closed, the following dialog box comes up
Select “Yes” if you want to import the rejected records into a secondary computer. If you know for sure, however, that you do not want to keep any of these rejected records (and, hence, it is OK that they were rejected), select “No.” Finally, if you accidentally select “No” here, do NOT redo the import; instead, contact the Coordinating Center so they can help you import the rejected records into a secondary computer.

If you select “Yes” in the above dialog box, the following dialog box comes up.

Here, please remove the data transfer diskette from the primary PC import and replace it with a blank, formatted, 3½ inch high-density diskette. Then click “OK.” The DMS then puts a compressed file that contains the rejected records (but none of the “accepted” ones) on the inserted diskette. Then the following dialog box is displayed.

Please remove the diskette then and label it using the labels supplied by the Coordinating Center. These labels look like this:

Under “Diskette Name & Date:”, please put the diskette name (e.g., CBMTX01REJ027) and the date. Here, please note that the name of this diskette is the same as that of the corresponding data transfer diskette used for the primary PC import except that it includes “REJ” before the given sequence number. Finally, after the rejected records have been successfully imported
onto a secondary computer, please note that you can reuse this “rejected records diskette,” after first deleting the files on it, for a future situation where you have rejected records during an import into the primary PC.

Finally, after you click “OK” on the above dialog box, the dialog box that says “Import complete” and “Process another data transfer diskette?” is displayed. At that point, you can insert another data transfer diskette that contains records to be imported into the primary PC.

Importing the Rejected Records into a Secondary Computer
Take the above rejected records diskette (in our example, diskette “CBMTX01REJ027”) to a secondary computer. Here, it is best to import the rejected records into a secondary PC that does not currently have any records on it (i.e., no data has been entered into the PC since its last export). However, it is not necessary to do that. Furthermore, the rejected records do not need to be imported into the same PC that they were originally exported from.

To import the rejected records into the secondary computer, log into the DMS and go to the Utilities menu (which is on the Main Menu). Then select “Import Rejected Records” (this option is only available on secondary computers).

Then, the following dialog box will come up.

Accordingly, please insert the rejected records diskette into drive A and click OK.

After the DMS checks that the diskette is valid, the records are imported just like records are imported into the primary computer. Then, just like on the primary PC, a “COMBINE Trial
DMS - Import Summary Report” is displayed. This import summary report looks just like the one for the import into the primary PC and its columns have the same meanings.1

Finally, after you have printed or closed the import summary report, a dialog box is displayed as in the primary PC import that says “Import complete” and “Process another data transfer diskette?” Here, click “Yes” if you want to import another rejected records diskette into the secondary computer. (However, please do not import another rejected records diskette into this secondary computer in the unlikely event that it has some of the same rejected records as the first rejected records diskette.)

**Resolving Rejected Records after they have been Imported into the Secondary Computer**

After a rejected record has been imported into a secondary computer, the first objective is to determine why that record was rejected if it is not already known. Then, the appropriate action can be taken on that rejected record OR on the corresponding record in the primary computer’s database.

Again, a record is rejected during an import into the primary PC if it has the same values for the key fields Study ID, Form Name, Week #, and Form Seq # as a record that is already in the primary database. There are two principal reasons why a record may be rejected.

**Reason 1 – Incorrect Key Field Value**

The value of at least one of the above four key fields is incorrect for either the rejected record or the record in the primary database. For example, week 10 instead of 12 may have been accidentally entered for the rejected record. (Note: if the wrong week, for example was entered for a form set, all of the records entered at that time for the form set will have this incorrect week #. For example, if week 10 instead of 12 was accidentally entered for form set W12A and this form set was then finished by the participant, each of the entered records in that form set—OCD, DRQ, PSS, and POM—will incorrectly have week 10 instead of 12.)

**Reason 2 – Record Entered Twice**

The values of all of the above four key fields are correct for both the rejected record and the record in the primary database. In that case, the same record was simply accidentally entered twice. For example, one person on the clinical center’s staff did not know that another person on the staff had already entered that record.

One thing that may help you determine why a record was rejected is the date and PC that the record was entered on and the date and PC that the record was last modified on. Also, it may prove useful to find out this information for the corresponding record on the primary computer as well. To find out this information, view the record in browse or change mode and then, from the “Display” menu, select “Entry Info.” (See section 4.7 for more information.) Please note, however, that the accuracy of each date displayed is dependent upon the accuracy of the given computer date at the time the record was entered or last modified. Finally, one reason why this information may prove useful is that it may help you determine if you entered the wrong week for a given form set, for example, because you may have a written record of what date the COMBINE participant came in for the various week visits.

---

1 Please contact the Coordinating Center in the unlikely event that these rejected records are again rejected during this import into the secondary PC.
Another thing that may help you determine why a record was rejected is to visually examine the rejected record as well as the corresponding record on the primary computer. Likewise, the “Print Form” report may prove useful here (see Section 6.2 for more information). This report lists the questions and responses for a given record in the database. You can use the “Print Form” report to compare the rejected record to the corresponding record on the primary computer.

Finally, once you know the reason why the record was rejected, you can take the appropriate action. For example, if one of the key fields (e.g., Week #) is wrong on either the rejected record or the record in the primary database, you can do a key field change on the appropriate record. Then you can export the rejected record from the secondary and import it—this time successfully—into the primary.

Another example is that you may have determined that the record was simply accidentally entered twice. Then, based on viewing both records and/or the associated “Print Form” reports, you can either delete the rejected record on the secondary or the corresponding record on the primary. If you delete the record on the primary, you can then export the rejected record from the secondary and then import it into the primary.

5.4 Primary PC to Coordinating Center Export and Data Transfer

Once every two weeks data collected in the Clinical Centers will be sent from each center’s primary computer to the Coordinating Center via Internet or modem. At the Coordinating Center, the consolidated COMBINE database will then be updated with the data from the sites. The export/data transfer process includes several steps—all of which are carried out on the Clinical Center’s primary computer:

1. A complete backup of the primary database is made to floppy diskette and the SECURE_DMS disk (usually a zip disk).
2. A data transfer file is created and put in a folder on the C drive.
3. The user exits the DMS and double-clicks on the “COMBINE Internet Data Transfer” or “COMBINE Modem Data Transfer” icon on the computer’s desktop.

Here, note that one big difference with the export from a secondary computer is that the data on the primary computer is not removed after the export.

To start the export process, in the primary computer DMS choose “Export Files” from the Utilities menu (a picture of this menu is in Section 5.1). The data in the DMS will then be backed up to the disk labelled “COMBINE Main Trial SECURE_DMS” (which is—in most cases in COMBINE—a 250 MB Iomega zip disk). Then the data will be backed up to the 3½” backup diskette(s) for the primary computer. Note: Please read Section 4.14 for a description of this backup process. Finally, please note that the database must be backed up to the backup diskette, or the export will be aborted.

After the backup has finished, the export begins. Records that—since the last export—have been added to the database, imported from a secondary computer, changed (either data change or key field change), or deleted are exported. Please note that the fact that deleted records are exported is a major difference between the primary computer’s export and a secondary
A deleted record is exported on the primary computer because that causes the corresponding record in the consolidated database at the Coordinating Center to be deleted as well.

The “COMBINE Trial DMS – Export Summary Report” is then displayed. Please see the introduction to Chapter 6, “Reports,” for the functionality of the buttons on the report’s toolbar.

This report is the same as the export summary report for a secondary computer’s export with the exception that this report includes the number of deleted records exported per form. Please see Section 5.2 for a description of the secondary computer’s export summary report.

Click the print button on the report’s toolbar to print and close the report. (Do not try to print the report if the computer is not connected to a local or network printer.) Click the X in the upper right corner of the report window to close the report without printing it.

Then, a compressed “transfer file” containing the exported records is created in a folder on the C drive. Then a message is displayed that says something like “Please Note This Transfer File Number CBMTX00034. Press any key to continue…” Here, the transfer file name has the same format as that for the secondary computer in that “CBM” stands for “COMBINE Main Trial,” “TX00” indicates that the export is from the primary computer TX00, and “034” is the export sequence number. Here, the first export from the given primary computer has sequence
# 00, the next has sequence # 01, and so forth. Finally, after you “press any key to continue,” the export is finished.

NOTE: If you get a fatal error during the export, restart the export process. Please contact the Coordinating Center if you continue to have problems or have any questions.

The next step in the export/data transfer process sends the transfer file, via modem or Internet, to the Coordinating Center.

Close the DMS by selecting “Quit” from the Main Menu. Then, from the computer desktop, double-click on the icon “COMBINE Modem Data Transfer” or “COMBINE Internet Data Transfer.” A script file runs which looks for files to be sent. If there are no files to be sent, you will receive a message. If there are files to be sent, the computer will send the files to the Coordinating Center.

Do not reboot the computer, stop pcAnywhere (the communications software used for transferring the data), or run the DMS after you start the script until the transfer is complete.

If you are transferring via an external modem, make sure the modem is connected to the computer and is turned on.

Please note that sometimes, during the first or second try, pcAnywhere will not be able to make a connection. Here, you will get a message that says “Timeout Looking for Connection.” Click “OK” to that message and then click “Cancel” when it automatically tries to send the file again (this automatic resending will not work). Then you will get a message like “Error Dialing Host” in the Notepad window that comes up (this window is described in more detail below). Then, after closing that Notepad window, just double-click again on the “COMBINE Internet Data Transfer” or “COMBINE Modem Data Transfer” icon to send the file.

As mentioned above, the results of the data transfer are appended to a transfer log file which is displayed in a Notepad window. Go to the bottom of the file and examine the message written during the last transfer. If the transfer was successful, you should see a message like the following:

********** COMBINE Data Transfer 01/15/2001 13:00:13 **********
Files transferred successfully

Examine the date and time to be sure you are looking at the correct log message.

If the transfer was unsuccessful you will see an error message such as

********** COMBINE Data Transfer 01/15/2001 13:00:13 **********
Error dialing host ERROR Number: 0 Host: CBICSCC $Error -15

***********************
In that case, try again immediately a few times as mentioned before. **If you are still unable to send the file, try again later that day or call the Coordinating Center for help.**

To exit Notepad, choose File/Exit from the Notepad menu.

### 5.5 Backup DMS to Diskette

The “Backup DMS to diskette” menu option on the Utilities menu can be used to back up the DMS. See Section 4.14 “Backing up the Database when Quitting the DMS (or when doing an Export etc.)” for more details on this back up process. Also, please note that you use this menu option to create a **new** Backup diskette #1 for a given computer. This is described in the “Making a new Backup diskette #1” subsection of Section 4.14.
6 Reports

The COMBINE Trial DMS includes three reports, the missing fields report, the print forms report, and the personal feedback report. To run reports, choose Reports from the main menu.

Each of these reports, as well as each report shown when exporting or importing data, is displayed in a window that can be resized, moved, maximized, closed etc.. Also, there is a toolbar associated with the report.

Moving your cursor over a button of the toolbar (without clicking the button) causes the function of the button to be displayed in a brief message. For example, moving your cursor over the icon with the printer on it causes the message “Print Report” to be displayed. Pay special attention to the buttons with triangles on them pointing left and right. If one of these buttons is not dimmed, there is more than one page in the report and you can click on the button to go to, for example, the next page in the report if the button has the triangle on it that is pointing to the right.

Finally, if you wish to send the given report to the default printer for the computer, click the button with the printer icon on it on the report’s toolbar. Note: printing the report also closes it. ALSO: do not try to print a given report if the computer is not connected to a local or network printer. Finally, if you wish to close a report without printing it, click on the X in the upper right corner of the report window.

6.1 Missing Fields Report

The Missing Fields Report allows the user to list fields which are empty or unresolvable for a record. (Empty skipped fields are not listed.) Also, note that on self-administered forms, if the COMBINE participant selects “Skip this question,” the given field is made unresolvable.

When you select this report option, the following screen is displayed.
Enter a COMBINE ID on which to report. Then enter the other key field information for the form of interest (Form+Version, Week, Form Sequence #).
If the record exists in the database and it has missing fields you get a report like the following.

If the form does not exist in the database or if it has no missing fields, you are notified.

Close or print the report to return to the report input screen. Press ESC or leave the Combine ID field blank and then press ENTER to exit the report input screen.

### 6.2 Print Form Report

The Print Form report prints data from one or more forms in the database. The question (or prompt) plus the value (or response) is printed but the output is not formatted to look like the paper form or the DMS screen. To print a form choose that option from the report menu. On the displayed screen, shown below, enter the identifying information for the forms you want to print. Enter a list of forms. Press F3 to display a list of all form mnemonics. Enter ‘X’ when you have finished entering forms and respond ‘N’ to the prompt ‘Add more forms’. Choose whether you want to View or Print the form.
6.3 Personal Feedback Report (PFR)

The “Personal Feedback Report” option in the Reports menu creates a summary that contains many of the scores that are to be filled in the PFR that is presented to the COMBINE participant. To create the report, select that menu option. Then enter the appropriate COMBINE ID and choose whether you want to view or print the report (see below). Finally, to exit the screen below, press Esc or leave the COMBINE ID blank and press ENTER.
A report that contains scores will not be generated under certain circumstances. Instead, the user can choose to generate a blank report in those cases. First, a report with scores will not be generated if there is not a completed TQS form in the DMS for the given COMBINE participant. The report gets the initials, gender, and age of the participant from the first TQS record entered in the DMS for him or her. Gender is needed for the determination of some scores—for example, the "Other Drug Use" percentiles. Second, the scores in the report are determined using the data from other entered forms as well (e.g., AED for "Other Drug Use"), and, if none of these other forms have been entered in the DMS (or have been entered as "Permanently Missing"), a message will be displayed that says "No relevant baseline data has been entered for this COMBINE ID…". In that case, only a blank report can be created. Here, note that, for these non-TQS forms, only records at Week 00 are utilized by the report. Furthermore, if there is more than one record in the DMS at Week 00 for a given COMBINE ID and form (e.g., AED), that record with the highest form seq # is utilized (which is usually the last Week 00 record entered for that participant and form).

The report is divided into sections that have the same names as the corresponding part of the PFR that is presented to the COMBINE participant (below is a view of page 1 of the report).
The sections in the DMS report are: "Alcohol Dependence Level," "Other Drug Use," "Consequences," "Preparation for Change in Drinking" (which is further divided into four subsections), and "Mood States." The scores in each of these sections (or subsections in the case of "Preparation for Change in Drinking") are determined using the form that is listed in the title of the given section (e.g., "SCD" for "Alcohol Dependence Level"). Finally, if one of these Week 00 forms has not been entered in the DMS for the given participant (or has been entered as "Permanently Missing"), then it will be in the "Missing Forms" list at the top of each page.

Supporting information for the scores that will be entered on the PFR that is presented to the participant is often included in the report. For example, in the "Readiness" subsection of the "Preparation for Change in Drinking" section on page 2 of the report, separate scores for each subcomponent of Readiness are listed. Likewise, for the "Other Drug Use" section on page 1, the number of days in which the given drug was used during the "Past 90 Days" period is given (and for Tobacco, the average number of cigarettes per day that the participant smoked—over those days that he or she did smoke during this period—is given).

A score will be left blank on the report for several reasons:

1. It will be left blank if the given Week 00 form is missing.
2. It will be left blank if it is the value of a single form response and that response is empty.
3. The score will be left blank if too many of the form responses used to compute the score are "absent" (i.e., are empty or unresolvable). In some cases—which are noted on the report—an imputation algorithm is utilized to estimate the values of absent form responses. For example, in the "Consequences" section on page 1 of the report (see the screen above), if 1 or 2 of the DRB responses being summed for "Physical Consequences," for instance, are missing, then an imputation algorithm is used to determine the values of these missing responses. Here, out of those \( X \) responses being summed, this algorithm assigns to each absent response the average—rounded to the nearest whole number—of the values of the present ones for that subscale, and then all \( X \) responses are summed. An asterisk * is then put after the score to indicate that an imputation algorithm was utilized in determining it.
4. The score will be left blank if a form response used to compute the score has an invalid value (here, such a response would have had to have been confirmed in the DMS when it was entered).

Finally, rounding of scores is utilized. Let \( y \) be a given score. Then, for example, if \( 2.40 < y < 2.45 \), then \( y \) is rounded down to 2.4, and, if \( 2.45 \leq y < 2.50 \), \( y \) is rounded up to 2.5. Likewise, if \( y = 2.35 \), \( y \) is rounded up to 2.4.
7 Remote User Service (via pcAnywhere)

Sometimes the CSCC must connect to a Clinical Center computer to diagnose or repair a problem. To allow the CSCC computer to control the Clinical Center computer we use a product called pcAnywhere. If you use a modem rather than the Internet for data transfer and user service, be sure that the modem is properly connected to the computer, connected to the phone line, and turned on. Of course, if you have a problem you must call us first to discuss the problem and to determine how to proceed.

To start pcAnywhere, click on the "Start" button in the task bar, put your cursor on "Programs" and then "pcAnywhere32," and then click on "pcAnywhere." Then follow the instructions of the person that you called at the CSCC.

The CSCC can then connect to your computer to diagnose and repair problems with the DMS.

In some situations it is not possible for your computer to receive a call on the available phone line or Internet connection, but it is possible for you to initiate the pcAnywhere connection. In this case, we will ask you to have your computer call us. If we determine that this connection method is required, we will give you a phone number for pcAnywhere to call or an Internet address for it to connect to.

While we are working on your computer using pcAnywhere, do not do anything on your computer unless we tell you to do so.
8 DMS Updates

During the course of the study, the Coordinating Center will distribute updates to the Data Management System software. These updates may include new or updated forms for data collection, new features or reports, and corrections for errors which are detected in the system. Each update should be installed as soon as possible after it is received at the Clinical Center.

Each update will include a memorandum detailing the changes to the DMS which are included in the update. On the Web, the DMS update memos are available at http://www.cscc.unc.edu/combine for viewing or downloading. Go to “Study Documents” on the web page, and then “Memos” and then enter the appropriate user name and password. Then, in the list that comes up, look for entries that begin with “DMS Update 1.1”, “DMS Update 1.2”, etc.. The entry for the update memo lists some of the features that came out in the update. For example, the entry for the DMS Update 1.2 memo is

DMS Update 1.2 (new form version, F2 features for dates and repeating values in CAL and PLC, WOC seq # 02 message)

When you have found the appropriate update memo in the list, click on “View” for that memo. To save the memo to your computer so that you can later print it, click on the button on the Adobe toolbar that looks like a floppy disk (see below).

Then give the document a file name and choose where you want to save it on your computer.
Appendix A - COMBINE Trial DMS Quick Start Instructions

These instructions are intended to serve as a quick reference for using the COMBINE Data Management System (DMS), and are not a substitute for mastering the content of the Users Guide.

Who do I contact if I have a problem / question / concern?

Contact Marston Youngblood or Kelly Tobin Murray at the COMBINE Coordinating Center. Voice: Marston (919) 962-3083; Kelly (919) 966-7825
Fax:  (919) 962-3265
Email: myoungblood@mail.cscc.unc.edu
     Kelly_Tobin@UNC.edu

Starting the System

Be sure to attach all cables (mouse, power) to the computer before you turn it on.
To start the Data Management System (DMS), use the mouse to double-click the “Combine Main Trial” icon on your computer desktop.
Log in by keying your user ID (often your initials) and your password. If you key the wrong user ID, go ahead and key your password. You’ll see the message “Login Failed.” Key both in again.

Shutting Down the System

To shut down, you must first close the DMS by selecting Quit from either the Main Menu or the ID Screen menu. Now back up the data to the backup diskette(s). Now you will see the computer desktop. Click the Start button (lower-left corner of the screen), choose Shut Down, then click OK. Wait for the computer to turn itself off.

Starting a Form Set

After logging in, you’ll see the Main Menu. Choose Data Entry. You will see the ID Screen. Key in the COMBINE participant’s Study ID, the appropriate form set code, the appropriate Week #, and the appropriate Form Sequence # (the default Form Sequence # is 01). Also, you want the COMBINE participant to enter the form set with self-administered mode turned on and it is turned on by default (see Section 4.1 for more details).

How do I interrupt a form set and resume it later?

If you must interrupt a COMBINE participant entering a form set in-progress, it’s best to finish the current form in the form set, then Cancel the following form. If you have only completed a few questions on the current form, you might choose to Cancel that form, which will cause those questions to be repeated when the participant resumes entering the form set.
To resume the form set, go to the ID screen and enter the same information you used to start the form set (i.e. Study ID #, Form Set, Week #, Form Sequence #) and the computer will automatically display the first form that you canceled.

**What are some of the options available during data entry?**

<table>
<thead>
<tr>
<th>Special Keys</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT+F12</td>
<td>In a self-administered form, enable/disable the Add Menu and the shortcut keys.</td>
</tr>
<tr>
<td>F2</td>
<td>Repeat values entered on the ID Screen (e.g., Study ID). In CALA, TLFA, and PLCA, repeat values entered for certain fields of the same kind or increment by one day the last date entered in certain date fields (see Section 4.15 for more info).</td>
</tr>
<tr>
<td>F3</td>
<td>Use in the Form Name field on the ID Screen to bring up a list of all of the forms and form sets in the DMS. Note that this is the only way to choose a version for a form that is earlier than the current version.</td>
</tr>
<tr>
<td>CTRL+U (or fill the field with equal signs)</td>
<td>Set a field to Unresolvable—use it when a value cannot be collected (e.g., a respondent refuses to answer a question) or when the value you did collect is suspicious and should not be used in analysis (sets the first status byte of the field to ‘U’).</td>
</tr>
<tr>
<td>CTRL+F</td>
<td>Use this to Confirm that an out-of-range value is accurate (sets the first status byte of the field to ‘C’).</td>
</tr>
<tr>
<td>CTRL+H</td>
<td>Use this to mark a field as having been checked and confirmed in response to a Coordinating Center data query (sets the first status byte of the field to ‘H’).</td>
</tr>
<tr>
<td>CTRL+N</td>
<td>Open a note log. When finished, choose Save or Cancel to either keep or drop the note log.</td>
</tr>
<tr>
<td>ALT+S</td>
<td>Save the current form.</td>
</tr>
<tr>
<td>ALT+N</td>
<td>Cancel the form (you’ll be asked “Are you sure?”).</td>
</tr>
<tr>
<td>CTRL+PageDown</td>
<td>Move to the next form. (Do not do this in a form set, since the system will move forward automatically as each form is completed.)</td>
</tr>
</tbody>
</table>
If you forget how to do something, browse through the menus. You’ll find the Move and Problem menus particularly useful: the Move menu contains navigational items (move forward / back, etc.), and the Problem menu includes items for handling problems with a field (Confirm field, Unresolvable field, Note log).

**How do I know a form set is complete?**

After the last form of a form set has been completed, the system will return to the ID Screen.

**I have some strange error message on my screen. What do I do?**

Please contact the Coordinating Center if you get an error message and tell them the exact message and what you were doing prior to seeing the message. In rare cases, you might see an error message other than our Fatal Error display. Such messages typically have Cancel and Ignore as options. Please contact the Coordinating Center before hitting either Cancel or Ignore. However, if no one is available, please choose Cancel (do **not** choose Ignore). Then please email or phone the Coordinating Center and tell them, again, the exact error message and what you were doing prior to seeing the message.

**Help! My computer is frozen. What do I do?**

Usually, the best thing to do is to restart the computer. Begin by shutting down the computer. First, try pressing CTRL+ESC to open the Start menu, then choose Shut Down. If the Start menu doesn’t appear, try pressing the computer’s restart button if one exists. If one does not exist, try turning off the computer by its power switch. The power switch will probably work on IBM and Dell model laptops. Typically, if a laptop doesn’t respond to the power switch, unplug the computer from electrical power, close the laptop cover, gently turn the laptop upside-down, open the battery cover and remove the battery for a few seconds. Once the computer is turned off, make sure all cables are connected tightly, then turn the unit on as you normally would.
10 Appendix B - COMBINE Data Transfer Checklist

Below is a checklist of steps to follow when transferring COMBINE data to the COMBINE Coordinating Center from the primary computer (a more detailed description of this process is in Section 5.4 of the Users Guide above):

1. Run “Export Files” from the “Utilities” menu on the COMBINE DMS on the primary computer. (See Section 5.4 in the Users Guide for details.)

2. Exit the COMBINE DMS.

3. From the computer desktop, double-click on the “COMBINE Internet Data Transfer” icon or the “COMBINE Modem Data Transfer” icon.

4. If you use an external modem to transfer the data, be sure that the modem is on.

5. A script file runs which looks for files to be sent. If there are no files to be sent you will receive a message. In that case, go back to step 1.

6. Sometimes, during the first or second try, pcAnywhere (the communications software used for transferring the data) will not be able to make a connection. Here, you will get a message that says “Timeout Looking for Connection.” Click “OK” to that message and then click “Cancel” when it automatically tries to send the file again (this automatic resending will not work). Then you will get a message like “Error Dialing Host” in the Notepad window that comes up. Close that window and then just double-click again on the “COMBINE Internet Data Transfer” or “COMBINE Modem Data Transfer” icon to try to send the file.

7. A Notepad window will come up that indicates whether the data transfer completed successfully. Go to the bottom of the displayed file and read the message.

8. If the transfer failed, try again immediately a few times as mentioned in step 6 above. If you are still unable to send the file, try again later that day or call the COMBINE Coordinating Center for assistance.