

Using the HALT-C Data Management System (DMS)

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I. Logging on to the HALT-C Data Management System

A. Logging On

When you receive your user account on the HALT-C DMS, you will be given the website address for logging on to the system. Since the HALT-C DMS is a Web-based system, you will need to use an Internet browser – Netscape or Internet Explorer – to access the system. See Hardware and Software in Section C-1 of this manual, for minimal requirements for using the HALT-C DMS.

ADEPT requires several specific browser configuration settings. Cookies must be enabled, JavaScript must be enabled, and Caching must be set to check for newer versions of stored pages "every visit"

During login, these settings will be tested automatically. If they are not set properly you will not be able to log-in. An error message will be displayed explaining what setting failed.

The first time you try to use the system, you may receive an ADEPT System Alert error message about your browser's configuration and the browser cache. Instructions on changing the configuration are printed on the page with the error message.

If you need to change the settings, exit from your browser after making the necessary changes, then restart your browser to return the HALT-C DMS Web site.

Once the browser configuration is set, you will see a login screen for the HALT-C Trial. Enter your user ID and password, and click on "Login".

The feature that automatically remembers user names and passwords should never be used in ADEPT. Use of this feature can compromise the confidentiality of your research data.



The first time you log into ADEPT Production you will be asked to provide an identifying question and answer that can be used to verify your identity if you forget your password someday. You must

provide this information before you are allowed to log into ADEPT. Once you do, you will not be asked for it again in the future.

Your identifying question and answer should be something only you can answer; you should choose something that would be hard for someone else to guess.

Poor questions:

What is your son's name?

What is your favorite color?

Good questions:

What was your second grade teacher's name?

Where did you hide your teddy bear when you were little?

Make sure you can remember the answer to the question. If you ever need to use the "Forgot Your Password?" option, ADEPT will prompt you to answer your identifying question, and will email you a new password only if you provide the correct answer. (In some cases, the password may be emailed to the DCC Data Manager--for example, if you have no email address on file). If you decide you want to change your identifying question and answer, use the "Change Password" page to update this information.

B. Password Re-Use

For security reasons, the ADEPT system requires that all users change their passwords at least once every 90 days. If you have not changed your password in the last 90 days, you will be informed that you must change it in the next 15 days or else you will be locked out of the system.

One thing you should be careful about when changing your password is that you do not re-use passwords that you previously created. ADEPT will not allow you to do this, and it may cause an error that will prevent your password from being synchronized correctly.

To avoid confusion and error messages, always pick a new password. The best passwords contain both letters and numbers; use the examples below for ideas for creating passwords that are hard to guess, but easy to remember. (Note that passwords must start with a letter.) For example:

go2thystore

hope4thebest

surv1v0r (substituting one for "i" and zero for "o")

bakers13dozen

If you get an error message indicating that you tried to re-use a password, make a note of which passwords were changed if any, and try to change them again to a password you have never used before.

If you have any questions, please contact the DCC.

C. Change Password/Identifying Question

If you decide that you would like to change your password or identifying question, you can easily do that yourself. Just log on into ADEPT and from the **Main Menu** click on **Admin Function** and then on **Change Password**. The following box will pop up. To change your password you need to fill in the lines under **Change Current Password**. Selecting the checkbox will enable you to synchronize your passwords for Production and Development. If you would like to have separate passwords you need

to uncheck the box, and current password change will apply to Production only. After you make all desired changes, click the OK button.

If you would like to change your identifying question, you need to click the Set "Forgot may password" Q&A button. Then enter your new question and answer, and click the OK button.

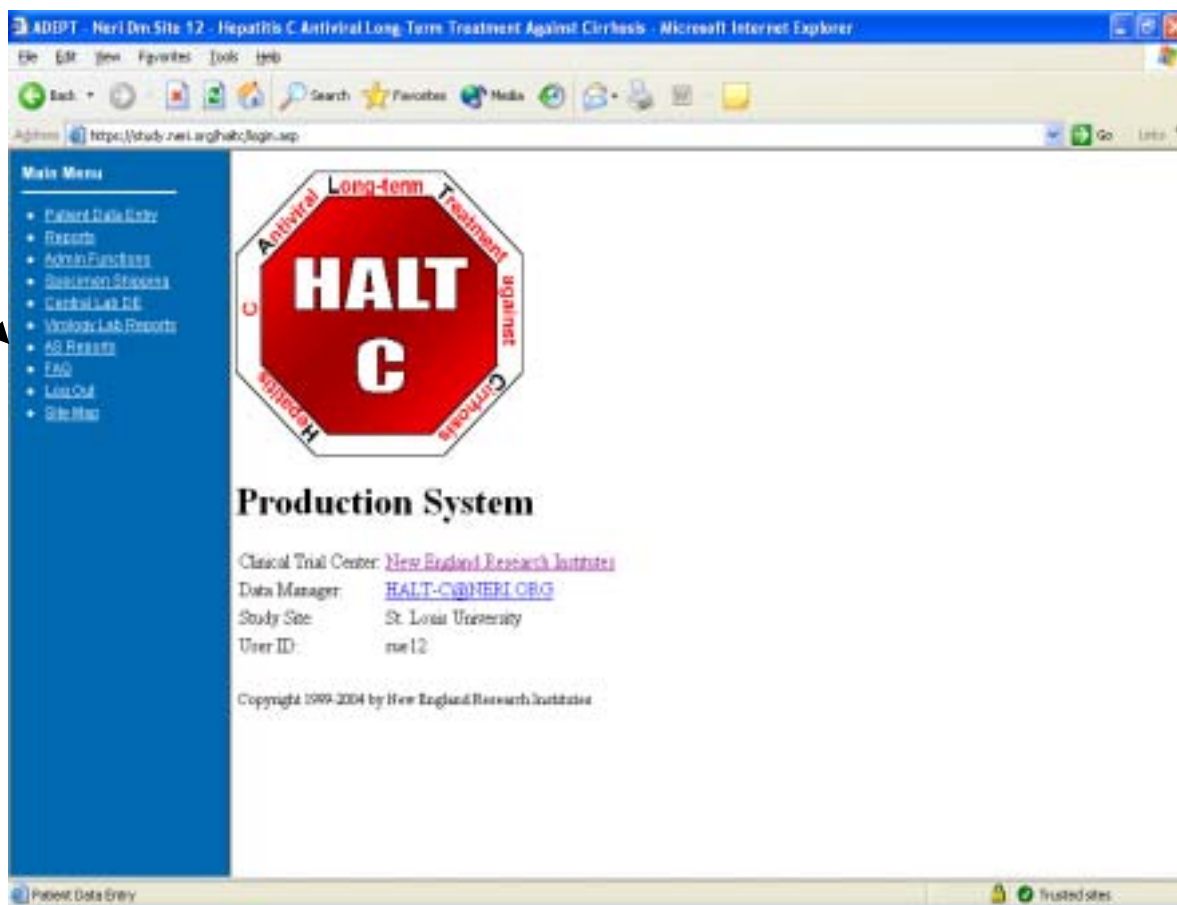
The screenshot shows a dialog box titled "Change Password/Identifying Info" with the following elements and annotations:

- Close button:** An arrow points to the 'X' icon in the top right corner with the text: "Close the window by clicking here and return to previous screen."
- Help button:** An arrow points to the question mark icon with the text: "Click on this button if you have any questions"
- Print button:** An arrow points to the printer icon with the text: "By clicking here you can print the information on the screen"
- Current Password field:** An arrow points to the first text input field with the text: "Type your current password"
- New Password field:** An arrow points to the second text input field with the text: "Type your new password"
- Confirm New Password field:** An arrow points to the third text input field with the text: "Type your new password again"
- Synchronization checkbox:** An arrow points to the checked checkbox with the text: "Check the box to synchronize all ADEPT passwords."
- Buttons:** At the bottom are "OK", "Cancel", and "Set 'Forgot My Password' Q&A" buttons.
- Q&A button:** An arrow points to the "Set 'Forgot My Password' Q&A" button with the text: "Click here to change your Identifying Question."

II. The DMS Main Menu

After you log in, you will see the **Main Menu** screen for the DMS:

Main Menu:
Click on
desired item

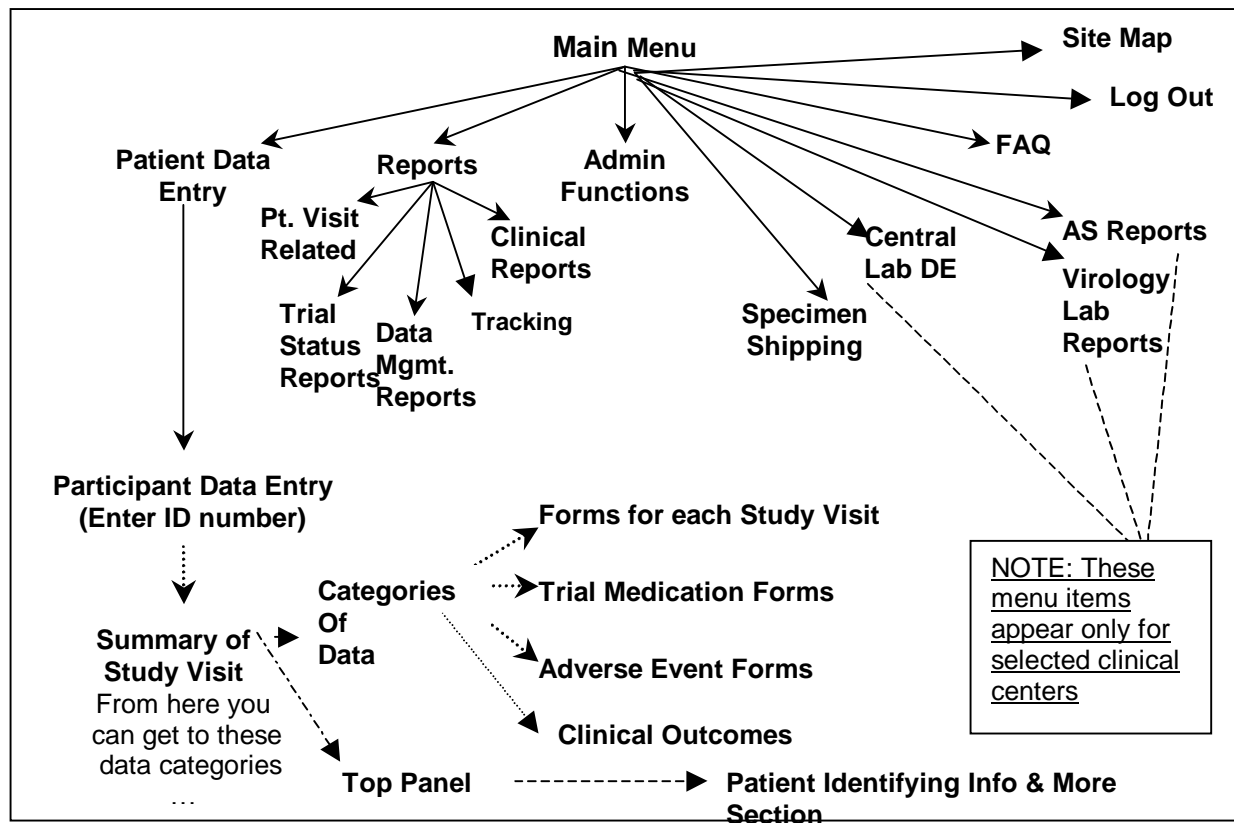


From the Main Menu screen, you can click on the following menu items:

- **Patient Data Entry:** Enter patient data forms. Print Visit Control Sheets. View data in forms that have been entered. Set patient appointments.
- **Reports:** Run HALT-C reports related to patient visits, clinical reports, trial status, data management, and tracking. Refer to section C-6 for a complete listing and explanation of some of the most frequently used reports.
- **Admin. Functions:** Change Password and System Announcements are under this function. You can use this menu to reset your password or Identifying Question. Important system and project announcements are saved under System Announcements. Any time-sensitive announcements will be displayed when you first log on.
- **Specimen Shipping:** Prepare and finalize shipments to the central Repository. Specimen shipping and tracking is explained in detail in Section C-5 of this manual.
- **Central Lab DE:** Used for data entry of forms that are completed at central labs, such as the Virology Lab or ancillary study central labs. Unless your user account was set up specifically for central lab data entry, no options will be available under this menu item.

- Virology Lab Reports: Used for reports related to forms that are entered at Virology Labs or Ancillary Study Central Labs, such as HCVRNA forms and Outstanding Lab Forms reports.
- AS Reports: Used for Immunology/Virology and QLFT Ancillary Studies tracking reports. Unless your clinical center participates in any of these Ancillary Studies, no options will be available under this menu item.
- FAQ: Read answers to frequently asked questions about using the ADEPT system (the system that the DMS is programmed in).
- Log Out: This menu item returns you to the HALT-C Login screen. Please log off of the HALT-C DMS when you are not actively using it.
- Site Map: Sometimes it may be confusing to find the report that you need. Site map will enable you to find the report you are looking for. More information on how to use this function is listed in Section C-6.

III. Map of the HALT-C DMS



IV. System Timeout

The HALT-C DMS is programmed using ADEPT. If you are logged into ADEPT for 20 minutes but have not performed any activity during that time, you will be automatically logged out. This is done for both security and web server efficiency reasons. A warning message will be displayed two minutes before this automatic logout occurs. If you want to stay logged on click on the appropriate button.

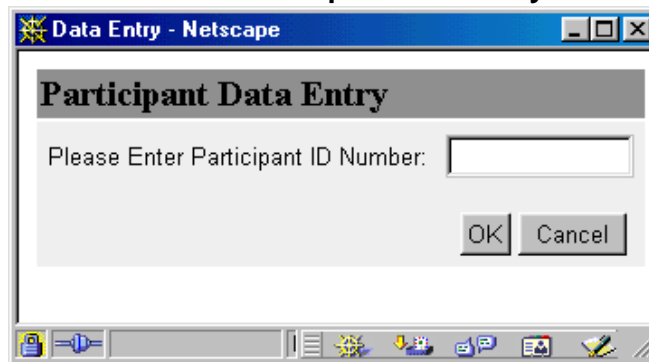
Any activities that cause the web server to execute a function will reset the 20-minute counter. Examples of this are entering an entire form, so data are saved in the database; running most reports; and preparing and finalizing shipments in the shipping database.

Sometimes you will be actively using the DMS and timeout warning message will be displayed. This is because some activities that you perform in ADEPT do not require running programs on the Web server. For instance if you are entering a long study form - and spend more than 20 minutes before reaching the end of the form - this message may appear, because keying in the data does not require any activity on the part of the Web server. In such instances, click on the "yes" button to reset the timer.

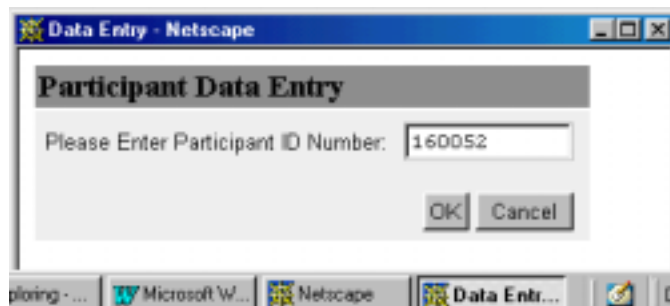
V. Adding a New Patient ID to the DMS

When a screening log entry is first completed for a patient, that patient receives a trial ID (patient ID). Before any data can be entered into the HALT-C DMS for that patient, the patient's ID needs to be added to the DMS. Adding a patient notifies the DMS that Form #1, Trial ID Assignment, will be entered in the DMS.

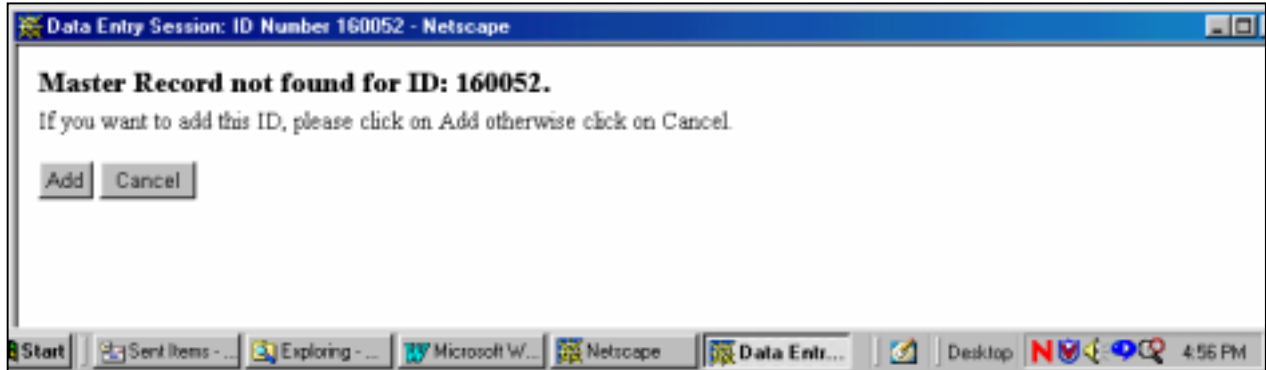
To add a new trial ID to the DMS, prior to entering Form #1: click on the Patient Data Entry menu item on the main menu screen. This small **Participant Data Entry** window will then appear:



Enter the patient ID listed on the top of Form #1, Trial ID Assignment, without the dashes. For example, if the ID printed on the label is 16-005-2, enter 160052. Click the OK button.



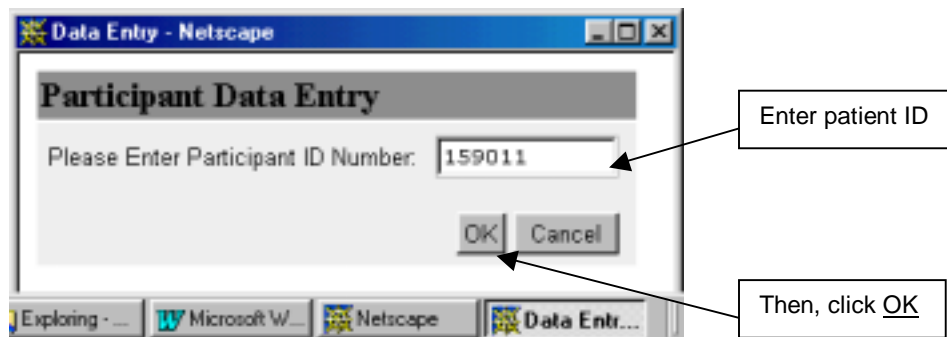
Since this is the first time this ID is being entered into the DMS, the following screen will appear.



If you typed in the ID correctly, click the Add button. If you made a mistake, click the Cancel button and try again.

VI. Locating a Patient ID

Once a patient ID (Trial ID) has been added to the DMS, you can move to the data entry screens for that patient by clicking on the Patient Data Entry menu item in the Main Menu. The **Participant Data Entry** screen will be displayed. Type the patient ID, and then click the OK button.



This will take you to the first screen related to patient data entry, the **Summary of Study Visit** screen.

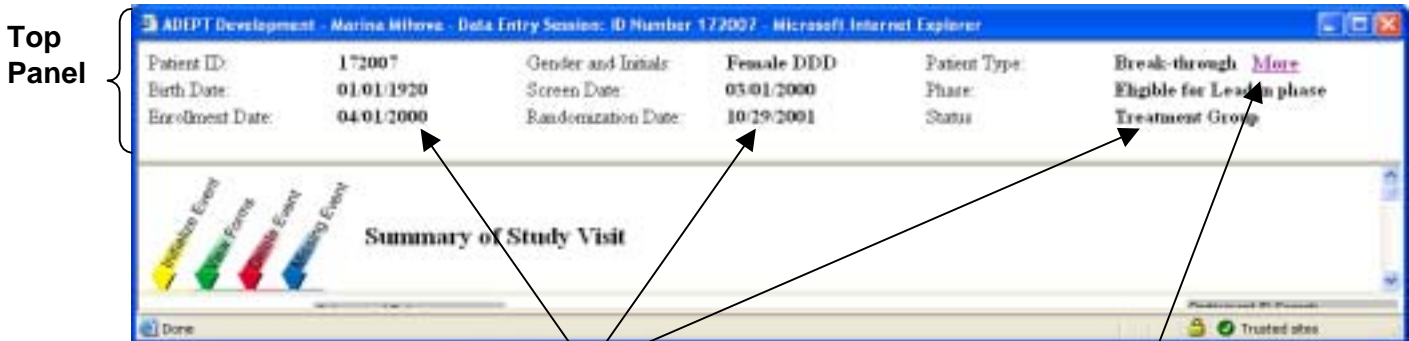
VII. Patient Identifying Information

Information that identifies a particular patient is displayed in the top panel of all screens related to patient data entry. Important pieces of patient-specific information are displayed once they are available to the DMS. When a patient ID is first added to the DMS, the only information the DMS has about the patient is the ID number. After Form #1, Trial ID Assignment, is data entered, gender, birth date, and initials are also displayed. As the trial proceeds, and more information about the patient is entered into the DMS, more information (i.e. screen date, enrollment date, randomization date, randomization status) will be displayed in the top panel of the screen. The information labeled "Phase" lists the patient's current trial status.

At the top right corner of the top panel you will see an item called More. By clicking on More you will view the Unusual Forms Report.

Example of Patient Identification Information

This patient “broke through”, and has since been randomized to the Treatment Group.



Top Panel

Patient Identifiable Information

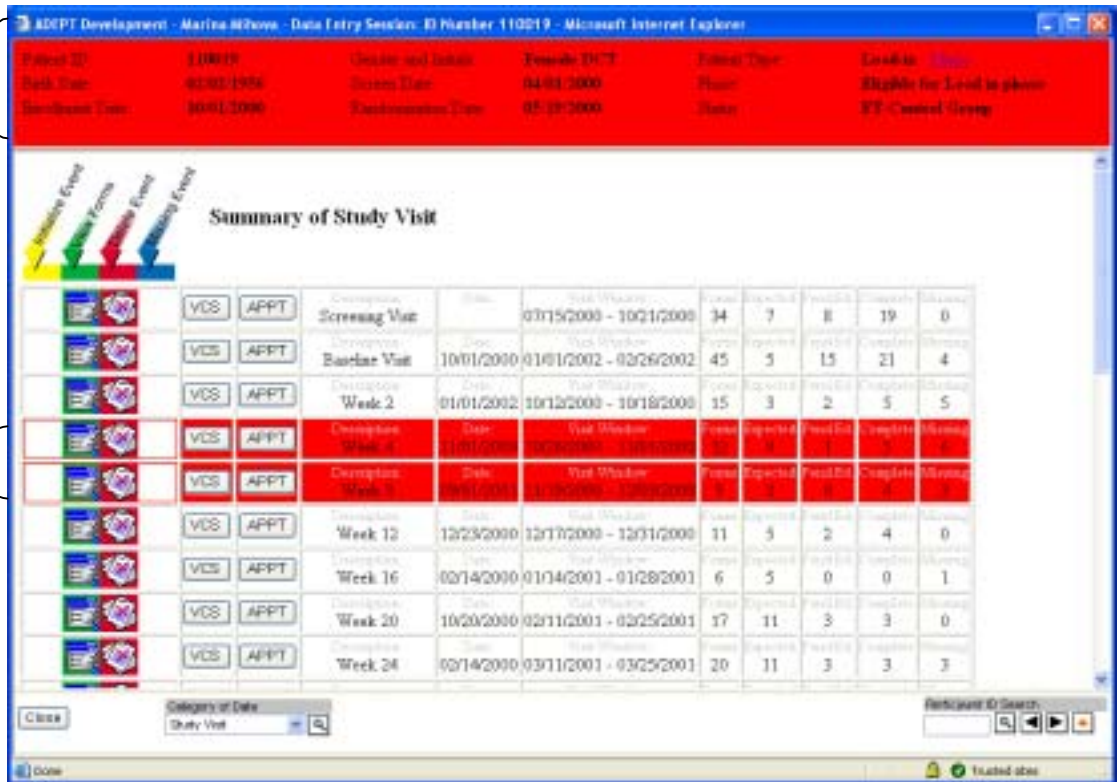
More – Contains a list of forms that are entered only in special circumstances, e.g. Form # 24, or 926.

Note: Once any of these crucial pieces of information about a patient are set in the DMS, they may not be changed throughout the course of the trial. For example, the patient’s initials are first entered into the DMS as part of Form #1, Trial ID Assignment. These are the initials that must be used for the patient throughout the duration of the study, even if he/she has a name change.

The top panel can be an identifier of what the status of the patient in the trial is. When it is red either Form #25, Early Termination, from Trial or Form # 64, Death report, has been entered.

Red color of the top panel identifies that the patient is no longer in the study.

The red color signals a missed visit. Forms # 24 and # 924 are data entered.



VIII. Early Termination and Patient Death

A. Early Termination

When the patient states s/he would like to withdraw from the trial.

When a patient withdraws before W72, or before M54, or dies before the end of the Trial, complete the following:

1. Complete Form # 25, Early Termination. This is an addible form. Add it to the patient's last completed visit. For example, if the patient finished M12 and is leaving before M15, enter the Form # 25 into the M12 visit.
2. Check all the medication logs to make sure they are complete and up-to-date. Once the patient has been randomized there should be a documented dose adjustment to "0" on Form #29 Ribavirin Dose Adjustments.
 - a. Control patients - Complete Form # 28 Peginterferon alfa-2a Dose Adjustment. Adjust the dose of peg down to "0". Then, complete Form # 26 Peginterferon alfa-2a Accountability. Record all returned vials of peg. The number of vials given out to the patient should equal the number dispensed. If not, complete a Form # 926 Lost Drug Accountability Log for lost drugs.
 - b. Treatment patients - Complete Form # 28 Peginterferon alfa-2a Dose Adjustment. Then, Complete Form # 26 Peginterferon alfa-2a Accountability. Record all returned vials of peg. The number of vials given out to the patient should equal the number dispensed. If not, complete a Form # 926 Lost Drug Accountability Log for lost drugs. The next step is to complete Form # 19 Early Termination of Pegasys Treatment if the patient is leaving before M48 visit. This is an addible form in the DMS. Add it to the visit that the patient stopped the peg. If the patient stopped the peg between two visits, add it to the later visit. For example, if the patient stopped the peg between M12 and M15, enter the Form # 19 into the M15 visit. If you do not know the exact date patient stopped Peginterferon, put date last peg was dispensed to patient in B1 and in B3 comment how many vials were given to patient on date of B1 and state you were not sure of when the last dose was taken.
3. Run tracking reports (Expected Biopsy, Endoscopy, Block, Tracking, CIDI and Site Freezer Inventory) by going to Reports/Tracking in the DMS. Make sure everything is sent to NERI or the appropriate lab or the Repository if applicable. Double-check the freezer for specimens that need to be sent for this patient.
4. Run the Detail Status by ID report for pending edits and expected forms by going to Reports/Data Management Reports. Run the Site Outstanding QC report by going to Reports/Tracking to show outstanding QC. Complete data entry for every form that is still outstanding, resolve edits and send outstanding QC to NERI.
5. Make sure all adverse events are resolved and so documented. Remember that if the Adverse Event became a Serious Adverse Event and the SAE is resolved, the Adverse Event should also be resolved.

B. Patient Deaths

1. Follow the same procedures outlined above if the patient dies, except do not complete a Form #25.
2. Complete the Form # 60 Adverse Event related to the death, if applicable.
3. Complete Form # 61 SAE related to the death, if applicable.
4. Complete Form # 63 Clinical Outcomes
5. Complete Form # 64 Death Report. This is an addible form in the DMS. Add it to the Adverse Event" Category.

Look in Form QxQs and the Manual of Operations Protocol for further information regarding completing of death, SAE and clinical outcomes forms.

IX. Screens Related to Patient Data Entry

A. Summary of Study Visit

The first screen that you encounter after entering a patient ID in the Participant Data Entry screen is the **Summary of Study Visit**.

From the Summary of Study Visit screen, you can:

- Access screens for entering and viewing data for a particular study visit;
- Access screens for data entry of trial medication log forms;
- Access screens for data entry of forms for adverse events and clinical outcomes;
- View whether any additional forms were entered for this patient by clicking on “More”;
- Display and print Visit Control Sheets; and
- Schedule and print patient appointments.

The **Summary of Study Visit** screen lists all the study visits for a patient for which data can currently be entered. For example, when a patient ID is first initialized, data can only be entered for the screening (S00) visit. After the completion of the Screening Checklist (Form #4), data can be entered for the baseline (W00) visit.

Note: To access data forms for a particular study visit, you must click on that visit in the Summary of Study Visit screen.

Example of a Summary of Study Visit screen

Top Panel containing Patient Information and More section

Study visits available for data entry. Click on the yellow icon to initialize the visit and enter data.

Click here to initialize the VCS for the respective visit.

Click here to open the screen for scheduling patient appointments.

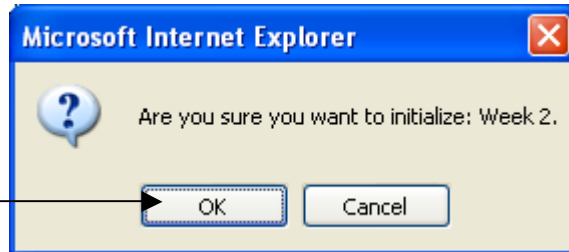
Visit	Category	Start Date	End Date	Days	Expected	Completed	Missed
Screening Visit	VCS APFT	02/01/2000	05/09/2000	14	11	0	3
Baseline Visit	VCS APFT	04/01/1998	03/29/1998	10	7	1	2
Week 2	VCS APFT	04/12/1998	04/18/1998	0	0	0	0
Week 4	VCS APFT	04/26/1998	05/02/1998	7	7	0	0
Week 8	VCS APFT	05/20/1998	06/03/1998	8	7	0	1
Week 12	VCS APFT	06/17/1998	07/01/1998	0	0	0	0
Week 16	VCS APFT	07/13/1998	07/29/1998	0	0	0	0
Week 20	VCS APFT	08/12/1998	08/26/1998	11	10	0	1
Week 24	VCS APFT	09/09/1998	09/23/1998	0	0	0	0

B. Elements of the Summary of Study Visit screen

• **Initialize Event:**

Before any forms can be entered for a study visit, the study visit (a DMS “Event”) needs to be initialized in the DMS. To do so, click on the yellow New button under the Initialize Event arrow. A window will appear asking you to confirm whether you want to initialize that particular visit. Click on the OK button if you intend to initialize the visit.

Click here to initialize this visit so that forms for that visit can be entered.



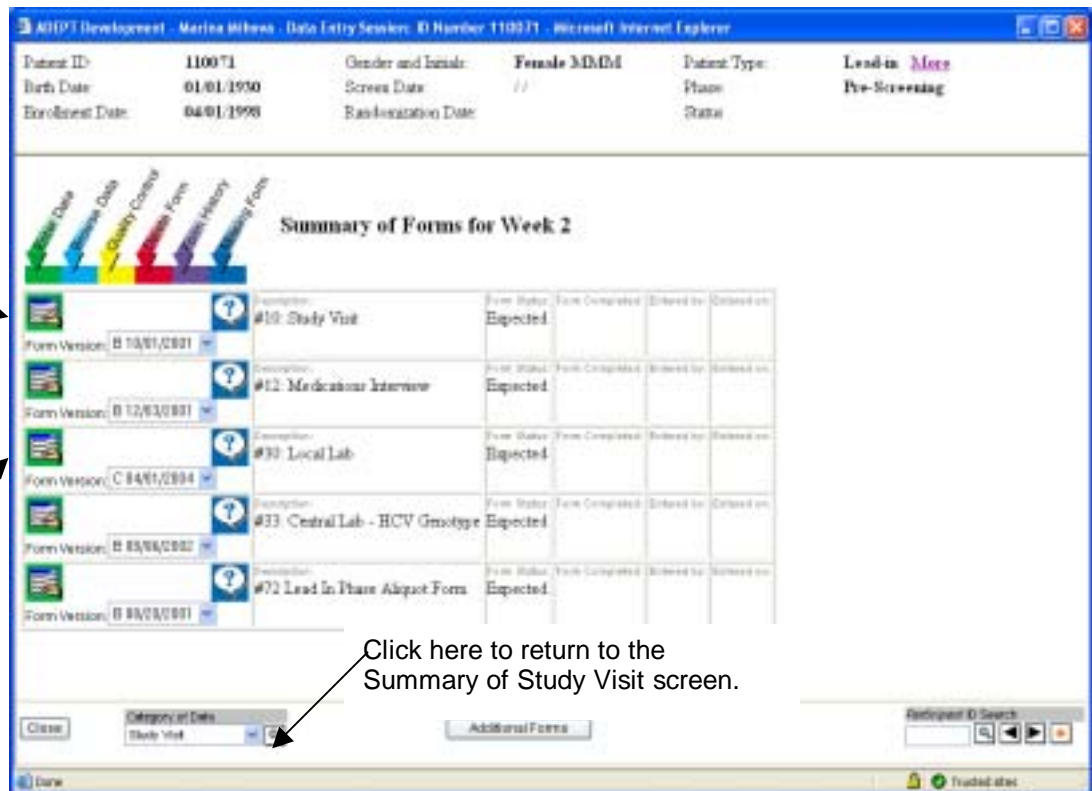
Once the study visit event is initialized the **Summary of Forms** screen for this visit will be displayed. See the detailed explanation of Summary of Forms screens, below.

• **View Forms:**

After a visit has been initialized, the yellow New button is no longer available on the **Summary of Study Visit screen**. Instead, a green View Forms button is available. Clicking on View Forms displays the Summary of Forms screen, which lists the forms that can be entered for that visit. The Summary of Forms screen is described in detail in Section C.

Click here to enter data in this form. In this case version B is available the default.

For this form version C is the default.



Click here to return to the Summary of Study Visit screen.

To get back to the Summary of Study Visit screen, click on the magnifying glass button on the lower left hand corner of the screen. Do not use the BACK button of your Internet browser.

In this example of the **Summary of Study Visit** screen, Form #4, Screening Checklist, has been data entered, indicating that screening is complete. Note that the baseline visit is also displayed. Once the baseline visit is initialized, data entry of forms expected at the baseline visit can be completed.

Patient information in the top panel: Notice the new information displayed after data entry of screening forms

Current trial status.

Click here to view and data enter forms for the screening visit.

Click here to initialize the baseline visit.

Click here to close this screen. This returns you to the Main Menu.

Display the VCS for this visit.

Schedule appt. for this visit.

Screening & baseline visit windows

screening forms still expected

screening forms pending edits

screening forms that are complete

Click on the magnifier to move to another "Category of Data". Or use the pull-down menu to choose "Adverse Event", "Study Medication Log" or "Clinical Outcomes".

Enter a trial ID here, then click on the magnifier to open another patient's records.

Opens the next or the previous patient's record

- **VCS:**

Display the Visit Control Sheet (VCS) for a visit by clicking on the gray VCS button on the Summary of Study Visit screen. Print the VCS by clicking on the printer icon that is displayed in the upper right hand corner of the VCS screen. Close the VCS by clicking on the close icon, next to the printer icon. Visit Control Sheets are explained in Section C-1.

- **APPT (Scheduling appointments):**

Clicking on the gray APPT button on the Summary of Study Visit screen moves you into the optional appointment scheduling portion of the DMS. See C-4, Data Entry and Related Tasks, for more information on scheduling appointments.

- **Delete Event (Caution!):**

The red Delete Event button should never be used! Choosing this button will erase the entire event, including all data in any forms associated with the event.

- **Missing Event:**

The blue Missing Event button should not be used to set an event to missing. If a patient will miss a visit, set the event to missing by entering Form #24, Missed Visit and Form #924, Alternative Study Visit, if applicable. Form #924 should be data entered whenever a randomized patient misses two consecutive visits.

- **Other information is displayed for each study visit:**

- **Date:** The date that a visit occurred (From Form #10, Study Visit, Question #A4).
- **Visit Window:** The beginning and end of the visit window for each study visit.
- **Forms:** The total number of forms to be completed for a visit.
- **Expected:** The number of forms that are expected by the DMS, but not yet entered.
- **Pending Edits:** The number of forms that have been entered, but are not yet complete. These are forms that need to have pending edits resolved.
- **Complete:** The number of forms for a visit that have been entered, with no pending edits.
- **Missing:** The number of forms for a visit that have been set to “Missing”.


- **Close:**

Use the Close button to close the Summary of Study Visit window and return to the Main Menu.

- **Category of Data:**

The Category of Data pull-down menu is used to choose between viewing forms related to study visits, trial medication tracking, adverse events, and clinical outcomes. To switch to a different category of forms highlight an option on the Category of Data menu and click on the magnifying glass button.

- **Participant ID Search:**

To do data entry or view forms for a different patient, type that patient’s trial ID in the Participant ID Search area, then click on  next to it. You can use the right or left arrows to move to the next or previous patient ID.

C. Summary of Forms Screen

To get to the Summary of Forms screen for a particular visit, click on the View Forms button on the **Summary of Study Visit** screen.

The **Summary of Forms** screen lists all the forms that are currently available for data entry. For example, when a patient ID is first added to the DMS, the only form that can be data entered is Form #1, Trial ID Assignment. A form can be opened by clicking on the Enter Data button for that form.

Summary of Forms for Screening Visit
(before any forms have been data entered)

Click here to close this window and move back to the Main Menu screen.

Click here to move back to the Summary of Study Visit screen.

Click here to display forms that can be added to this study visit, such as Form #5, Trial Ineligibility.

After Form #1 is data entered, Form #3, Screening Medical History Interview, becomes available for data entry and will be displayed on this screen.

Note that the patient-specific information that was displayed on the Summary of Study Visit screen is at the top of this screen, too. This information will **always** be displayed when you are in the Patient Data Entry part of the DMS.

There will be a **Summary of Forms** screen for each study visit. In addition, there are **Summary of Forms** screens for adverse event forms and logs, clinical outcome forms, and trial medication logs.

Summary of Forms for Screening Visit
(after data entry of several screening forms)

The screenshot displays a web browser window titled 'ADEPT Development - Teresa Curto - Data Entry Session: ID Number 159061 - Microsoft Internet Explorer'. The patient information section includes: Patient ID: 159061, Gender and Initials: Female CBA, Patient Type: Lead-in More, Birth Date: 10/10/1950, Screen Date: 09/01/2000, Phase: Eligible for Lead in phase, Enrollment Date: 09/01/2000, Randomization n., Status: Responder.

The main section is titled 'Summary of Forms for Screening Visit' and contains a table of forms:

Description	Form Status	Form Completed	Entered by	Entered on
# 1: Trial ID Assignment	Complete	08/28/2000	SSCHNEPS	10/19/2000
# 3: Screening Medical History	Complete	08/31/2000	SSCHNEPS	10/19/2000
# 4: Screening Checklist	Complete	09/01/2000	SSCHNEPS	10/19/2000
#11: Physical Exam	Expected			

Annotations and their corresponding elements:

- Click here to view this form's data entry history. (Points to the 'Browse Data' button for form #1)
- Click here to enter data in this form. (Points to the 'Enter Data' button for form #1)
- Click here to close this window and return to the Main Menu. (Points to the 'Close' button)
- Click here to return to the Summary of Study Visit screen. (Points to the 'Additional Forms' button)
- Click here to display and add additional forms appropriate for this type of visit. (Points to the 'Additional Forms' button)
- Form status (Points to the 'Form Status' column header)
- Date form completed (Points to the 'Form Completed' column header)
- Date form was entered (Points to the 'Entered on' column header)

D. Elements of all Summary of Forms Screens

• **Enter Data:**

Clicking on the green Enter Data button for a form moves you into the data entry screen for that form. This is the button you will use most often. Note that the form version is printed under this button. Form Version A is the initial version of the form. If a form is changed and there are multiple versions of a form, the form version will display a pull-down menu, so that the correct version of the form can be chosen for entering data.

• **Browse Data:**

Clicking on the blue Browse Data button for a form moves you into a screen that will allow you to view the data that has been already entered in the form without making any changes to it. The safest way to just browse the data without making any undesired changes or edits is by using the blue Browse Data button. Once you are in the form screen, use the <Tab> or <Enter> buttons to scroll down and view all data questions and answers.

• **Quality Control:**

The yellow Quality Control button is used by the DCC for double data entry of forms.

- **Delete Form** (Caution!):

The red Delete Form button is used to delete a form that has already been entered. If this is done, all of the data contained in the form is deleted from the DMS. The DMS will prompt for confirmation prior to deleting the form. When the form is deleted the DMS will check if the form was required as part of the protocol. If so, the status will be reset to “Expected”. If the form was manually added and not originally part of the study protocol for that visit, the form will be removed from the visit entirely. Certain forms should never be deleted because they trigger expectancies for events in the DMS.

Note: Always call the DCC before deleting a form. Once a form is deleted, it cannot be restored. If it has been deleted in error, it will have to be entered again.

- **Form History:**

The purple Form History button is used to view or print a detailed list of the form's history within the DMS. Form history includes the name of the person who entered the form, the date it was entered, and information about overrides, edits, and current form status. Each time the data on a form is changed in the DMS, the old value, new value, time and date of the change, and the name of the person who made the change are logged in the form history.

- **Missing Form:**

The blue Missing Form button is used to set an “Expected” form to “Missing”. This is used when all efforts to collect the data have been exhausted. “Missing” is a final disposition for the form. More information with instructions on how to set a form to missing is given at the end of this section.

- **Form status:**

The Form Status box displays the current data entry status of each form. The possible codes are:

- Expected: Required by protocol, not yet entered
- Pending edits: Entered but edits need to be resolved
- Complete: Form entered with no remaining edits
- Missing: All efforts to collect data recorded on the form have been exhausted. This form will never be entered for this visit.

- **Form Completed:**

The Form Completed box displays the date that a form was completed (the date from section A of the form).

- **Entered By:**

The Entered By box displays the user name of the person who entered the form.

- **Entered On:**

The Entered On box displays the date the form was entered into the DMS.


- **Close:**

Use the Close button to close the window and return to the Main Menu.

- **Additional Forms:**

Some forms are not expected by protocol at particular visits, but may be completed and data entered as necessary. Some examples are Form #5, Trial Ineligibility, and Form #24, Missed Visit. Additional forms are listed by number on the Visit Schedule, but are not expected at any study visit. To add one of these forms to the list of forms that can be data entered, click on the Additional Forms button. A screen will appear that displays the additional forms available for data entry. Highlight the form you wish to add and click OK.


E. Types of Summary of Forms Screens (Categories of Data)

To switch to forms for a different Category of Data, use the Category of Data pull-down menu and click on the magnifier icon  on the bottom left of all Summary of Forms screens.

- **Summary of Forms:**

There is a screen for each study visit that displays all the data forms that are expected to be entered at that visit. The Visit Schedule in Section B-5 of this manual lists all the forms expected at each HALT-C study visit.

Data for a particular visit must be entered in the forms for the correct study visit. For example, if you want to enter the W02 Study Visit form (#10), you must go to the Summary of Forms for Week 2 Visit screen, and then click on Enter Data for Form #10. The DMS will not allow you to enter week 2 data into forms under any other study visit. Similarly, the DMS will not allow you to enter data from any other study visit under Week 2.

To move from the Summary of Forms screen for one visit (e.g. baseline) to another visit (e.g. week 2), you need to return to the Summary of Study Visit screen by clicking on the magnifier icon  on the bottom left of the screen.

- **Summary of Forms for Study Medications Log:**

This screen is used to enter data into the log forms related to trial medications:

- Form #26, Peginterferon alfa-2a Accountability Log
- Form #27, Ribavirin Accountability Log
- Form #28, Peginterferon alfa-2a Dose Adjustments
- Form #29, Ribavirin Dose Adjustments

- **Summary of Forms for Adverse Events:**

This screen is used to enter data into forms related to adverse events:

- Form #60, Adverse Event Report
- Form #61, Serious Adverse Event Report
- Form #64, Death Report
- Form #68, Pregnancy Report

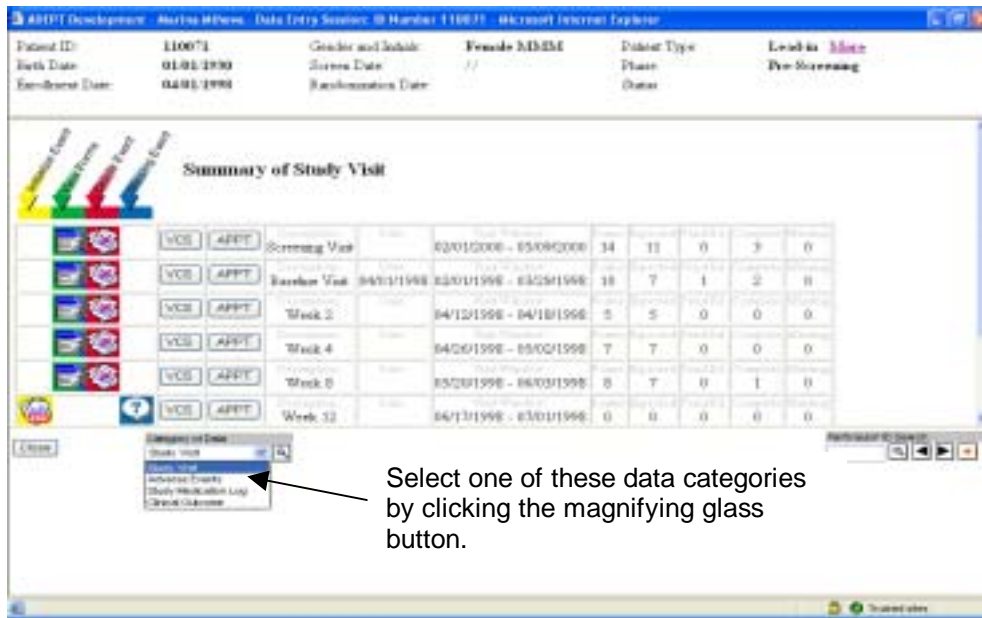
- **Summary of Forms for Clinical Outcome:**

This screen is used to enter data into forms related to clinical outcomes:

- Form #56, HCC Pathology
- Form #63, Clinical Outcome
- Form #65, Clinical Outcome Review
- Form #66, HCC Diagnosis
- Form #67, Liver Transplant Date

- **Unusual Forms Report (listed under More):**

- Form #19, Early Termination of Peginterferon alfa-2a Treatment
- Form #24, Missed Visit
- Form #25, Early Termination from Trial
- Form #155, Cognitive Effects Withdrawal Form
- Form #176, Immunology and Virology Withdrawal Form
- Form #194, QLFT Withdrawal Form
- Form #924, Alternative Study Visit
- Form #926, Lost Drug Accountability



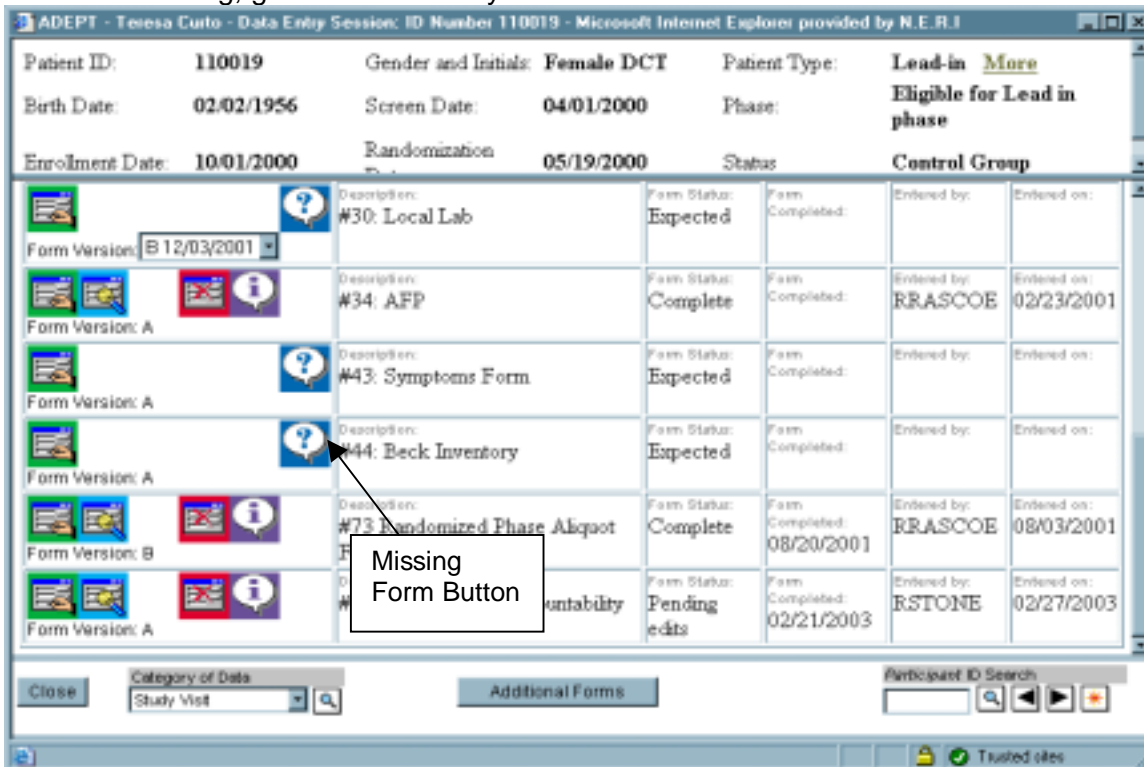
Select one of these data categories by clicking the magnifying glass button.

X. Setting Forms to Missing

The blue Missing Form button is used to set an "Expected" form to "Missing". This is used when all efforts to collect the data have been exhausted. "Missing" is a final disposition for the form. It should only be used only when site staff are certain that the data were not and will not be collected.

When setting the status to Missing, the DMS will prompt for an explanation. Missing reasons are stored within the DMS and reviewed periodically. Please provide informative reasons explaining why forms are missing. For example, recording and entering "missing" is not a sufficient explanation for a missing form. Explanations such as: "Patient refused", "Patient too tired" or "Interviewer omission" are examples of valid and useful explanations.

To set a form to missing, go to the Summary of Forms screen for that visit:



Missing Form Button

Click on the blue Missing Form Button next to the form you want to set to missing. You will see this screen:

Enter an explanation and your initials and click OK. This will bring you back to the Summary of Forms screen. The blue Missing Form button still looks the same, but the green Enter Data button has disappeared.

Description	Form Status	Form Completed	Entered by	Entered on
#30: Local Lab	Expected			
#34: AFP	Complete	Completed	RRASCOE	02/23/2001
#43: Symptoms Form	Expected			
#44: Beck Inventory	Missing			
...	Complete	Completed	RRASCOE	08/03/2001
...	Pending	Completed	R.STONE	02/27/2003

Write "missing" and the reason missing at the top of the paper copy of the form. File in the patient's notebook.

To reset the form to expected, click on the Missing Form button again and click “reset to expected”.

ADEPT - Tenessa Castro - Data Entry Session: ID Number 110019 - Microsoft Internet Explorer provided by N.E.R.I

Patient ID:	110019	Gender and Initials:	Female DCT	Patient Type:	Lead-in More
Birth Date:	02/02/1956	Screen Date:	04/01/2000	Phase:	Eligible for Lead in phase
Enrollment Date:	10/01/2000	Randomization Date:	05/19/2000	Status:	Control Group

Enter Missing Form Reason
 #44: Beck Inventory

Patient did not return the form.

Provided by: TMC
 Provided on: 9/23/2003

OK Cancel **Reset to Expected**