

HALT-C Data Management System Data Entry and Related Tasks

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I. Data Entering Study Visit Forms (forms expected at particular study visits)

From the Summary of Forms for Screening Visit screen, click on the green Enter Data button. The data entry screen will appear. The example below shows the data entry screen for Form #1, Trial ID Assignment.

Patient information in the DMS at this time

Cancel (exit form without saving changes)

Help

Form level comment

Field level comment

View Edit Report

Go To Field

Other Commands: RS Summary Comment/Override

Data entry fields

A. Information about Data Entry Screens

- In order to facilitate accurate data entry, the data entry screens are designed to look like the paper copy of the form.
- The DMS uses a form data entry system that scrolls the form vertically up the screen as data are entered, and prompts the user for the response to each question.
- The data entry screens automatically handle skip patterns by not displaying or prompting for answers to questions that should be skipped.
- Fields in forms must be entered in the order that the questions appear. Use <Enter>, <Tab> or a mouse click to move forward, from field to field, in a form.
- During data entry you can use your mouse to return to previous questions.

Note: The data keyed into a form are not saved in the database until the end of the form is reached. When you enter the last question on a form, the data in the form are automatically saved in the DMS. At the bottom of each form data entry screen there is a small box, where the cursor will hover while the data are being saved. Once the data are saved, the message, "The record was successfully added to the database" will be displayed, and you will be returned to the Summary screen. For longer forms, a temporary save function has been programmed into the DMS so that if the internet connection is lost before reaching the end of the form, a portion of the data is saved.

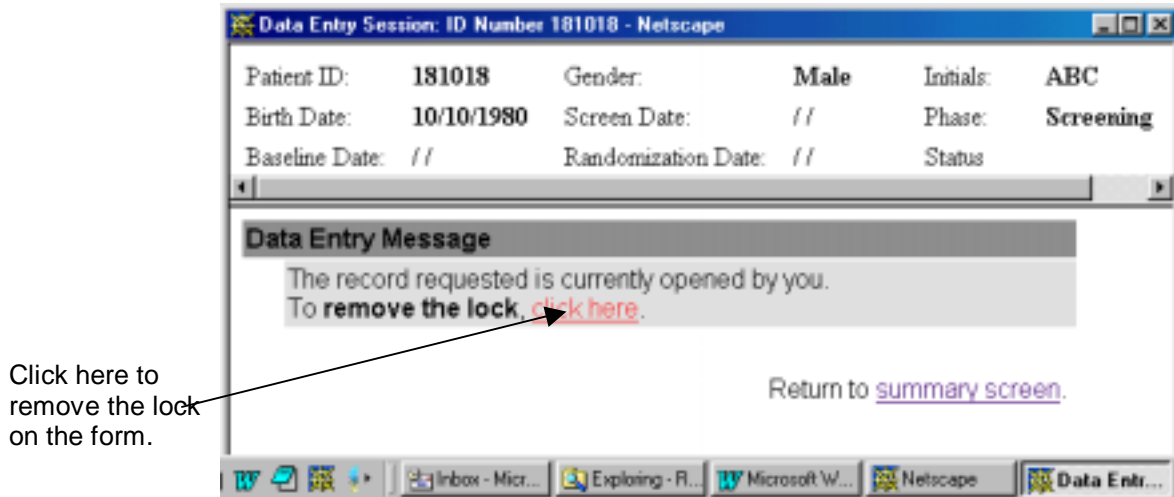
- **Entering patient IDs:** When entering patient IDs, do not enter the dashes. For example, if the ID printed on the patient ID label is 15-100-5, enter 151005.
- **Entering dates:** Dates should be entered in MM/DD/YYYY format or MM/YYYY format, depending on the question on the form. The help (?) button will tell you what formats are allowed (see below). Note: The slashes (/) in the date must be data entered.
- **Data entry of certain questions requires choosing between two sets of units (such as lbs. or kg.).** The help text for those questions, displayed by clicking the "?" button, explains how to enter data for the correct set of units.

Buttons on the bottom of the data entry screen: This is a brief summary of the buttons that are located at the bottom of the data entry screen. See specific sections in this manual for more information on each item

- **Cancel:** If you want to exit from a form that you are entering, click on the Cancel button. A small pop-up screen will ask you to confirm. Note: All changes to the form, and any data entry up to that point, are lost when you exit before reaching the end of a form.
- **Help (?):** A brief help message, geared toward data entry, is available for each question, by clicking on the help button.
- **Form Level Comment:** Clicking this button allows you to type in a comment that applies to an entire form.
- **Field Level Comment:** Clicking this button allows you to type a comment that applies to a particular question.
- **Edit Override:** Clicking this button will allow you to modify an override that has been entered for a particular question.
- **View Edit Report:** Clicking on this button allows you to look at the list of pending edits for this form. The edit report is displayed automatically when the last question on a form is data entered.
- **Go To Field:** This button takes you to any field in the form, without having to manually tab through the form.
- **Other Commands:** Choose to see the repeating segment summary or to field/form level comments and overrides
 - i. **RS Summary** – displays data entered in all repeating segments that were entered in the form.
 - ii. **Comment/Override** – brings up all form and field level comments that were entered in this form. Brings up list of all fields that were overridden and the override reason.

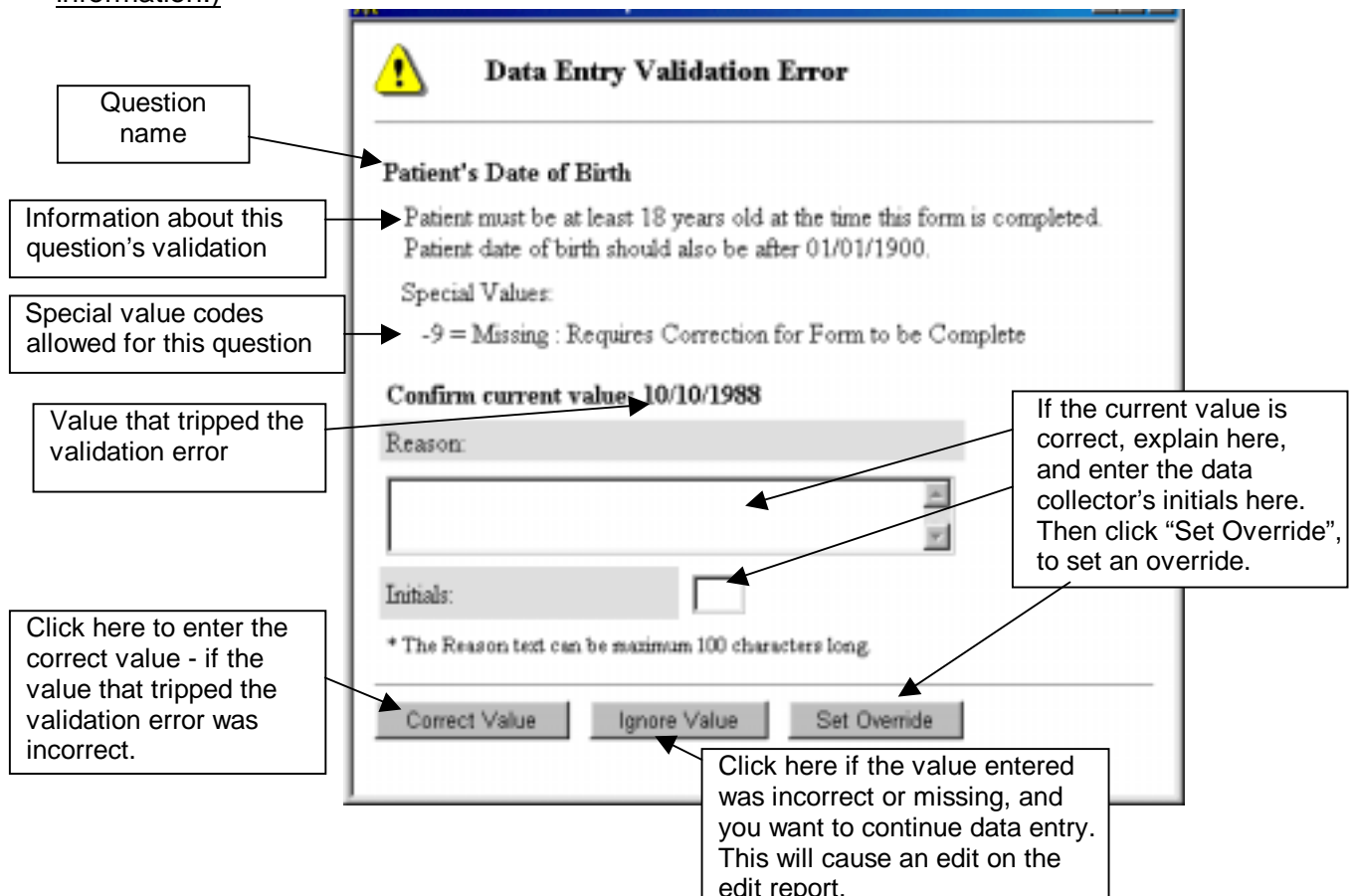
B. Locked Forms

If you accidentally exit a form (without using the Cancel button or reaching the bottom of a form), the next time you try to enter data into that form, you will see the following Data Entry Message. In this situation, click on "click here", which returns you to the Summary screen. You should now be able to enter data into the form.



C. Validation Errors

On-line validation is performed on each value as it is entered. If a value fails a validation test, a Data Entry Validation Error screen will explain the validation, giving the acceptable ranges for this question and provide options for what to do next. (Note: Pressing the Help ? button on the bottom of the screen also displays validation information.)



Depending on the question that tripped the validation error, one or more of these options will be available on the Validation Error screen:

Option 1:

Correct Value	<p>Correct the data entry errors If you entered a value incorrectly, click on the <u>Correct Value</u> button, and you will return to the data entry screen. This will enable you to correct the value and continue data entry.</p>
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Option 2:

Ignore Value	<p>Temporarily ignore error Ignore for now. Creates Pending Edit and Edit Report. Different validations have different levels of validation rigidity (strictness). Some variables are so critical that you cannot proceed without correcting the entry. For example, patient ID number and patient initials must be entered correctly for data entry to continue. Other validation tests that are not as critical allow you proceed to the next question by clicking the <u>Ignore Value</u> button in the Data Entry Validation Error screen. Although the validation failed, you can continue data entry. An edit report will be displayed when data entry is completed for a form, and the form's data entry status will be "Pending edits". All failed validations will appear in the edit reports and require resolution.</p>
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Option 3:

Set Override	<p>Give reason and initials If the data collector has provided a written explanation on the form next to the value that triggered the error, an override can be entered at that point. Doing so will avoid an edit on the edit report. If an adequate explanation is provided in the margin, enter the explanation and the data collector's initials and click the <u>Set Override</u> button in the Data Entry Validation Error screen.</p>
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D. Edit Reports

If there are missing data or other pending edits in a form, an Edit Report screen will automatically be displayed after the last field is entered. The Edit Report can also be displayed at any time during data entry by clicking on the View Edit Report button at the bottom of the data entry screen.

This Sample Edit Report demonstrates how the edit report needs to be filled out. Step-by-step directions on how to handle an Edit Report are also listed.

Sample Edit Report

Participant ID and visit → Participant ID : 159011 Screening Visit

Form name and number → Hepatitis C Antiviral Long-term Treatment against Cirrhosis # 1: Trial ID Assignments

Print by clicking this icon → [Printer icon]

Close edit report → [Close icon]

Question # & description → B1 Patient's Date of Birth

Value causing the validation error (edit) → Current Value: 08/15/1871

Validation text/help text → Patient must be at least 18 years old at the time this form is completed. Patient date of birth should also be after 01/01/1900.

If value is incorrect, write correct value here. → Correct Value

If value is correct, explain here. → Reason:

Data collector's initials. → Initials: _____
Data Collector

One of these boxes must be checked. → Value is 08/15/1871 Correct Value

How to handle an Edit Report:

- When the edit report screen appears, print the Edit Report by clicking on the printer icon.
- Give the edit report to the data collector to obtain the correct answer.
- The data collector fills out the edit report with the correct values.
- The data collector makes corrections on the paper form and puts his or her initials and the date next to the changes.
- Make corrections in ADEPT. If the value is to be overridden, use the reason provided on the edit report.
- Staple the edit report to the form before filing.

E. Special Value Data Entry Codes

For some questions, a special value code is an acceptable entry. The list of acceptable special value codes for a question is listed in the help message (? button) for each question. Some questions (such as patient ID or patient initials) do not allow any special codes.

-1 or 01/01/0101 (for date fields)	<u>not applicable</u> - The special value code, -1 (not applicable), is also used during data entry of certain questions that require choosing between two sets of units. If this is the case, the help text (?) for a question will specify that -1 is acceptable
-4 or 04/04/0404	<u>illegible</u> – a code used temporarily by data entry personnel until the value is clarified
-7 or 07/07/0707	<u>patient refuses</u> - interview forms only. Indicates that the patient refuses to answer to the question.
-8 or 08/08/0808	<u>don't know (DK)</u> - interview forms only. Indicates that the patient does not know the answer to the question.
-9 or 09/09/0909	<u>missing</u> –can be used temporarily until clarification is provided or as a permanent code.

-9 as a Permanent Code - In this case -9 (missing) should be used only if there are no means available to obtain the data, such as questions missed in interviews or lab tests not done.

-9 as a Temporary Code - The special value code, -9 (missing) may be useful during data entry, if a question answer is missing from a form without an explanation. In this situation, the special value code -9 can be used temporarily for this question until the correct values are provided. An edit report will be created. It will note that the answer to this question is missing, so that it will be possible to go back to the data collector to obtain the missing answer and enter the correct information at a later time.

Using special value codes:

Special value codes can be entered into the DMS by data entry personnel whenever data collection personnel write in an explanation appropriate for using a code, e.g., an interviewer writes, “the patient refuses”, with initials and date. In this situation, the data entry personnel would data enter -7 (07/07/0707 for dates), if that was an acceptable code for that question.

The special value code, -9 (missing, 09/09/0909 for dates) may be useful during data entry if a question’s answer is missing without an explanation. In this situation, the special value code -9 (or 09/09/0909) can be entered for this question. When the Validation Error screen appears, choose the Ignore Value option; at the end of entry, an edit will be generated for this question. The resulting edit report will note that the answer to this question is missing, so that it will be possible to go back to the data collector to obtain the missing answer. If the data will never be available, you may be able to set an override to explain that, depending on the question’s rigidity.

The special value code, -1 (not applicable), is used during entry of certain questions that require choosing between two sets of units. If this is the case, the help text (?) for a question

will specify that -1 is acceptable. For example, doses of interferon can be specified in MU or mcg units, depending on the type of medication taken. For questions asking for dose of interferon, use the special code -1 during data entry to indicate the set of units that is not applicable. The help text for these questions explains how to use this value.

F. Repeating Segments

Some questions such as the dates and reasons that doses of trial medication were missed (question D4 on Form #10, Study Visit), may require a varying number of responses, depending on the patient or the study visit at which the form is completed. Repeating segments are used for entering the answers to questions that have a number of responses that differs depending on circumstances. A segment refers to a group of questions that may have the varying number of responses.

In the example below, question D4 is a repeating segment in the DMS that allows entry of the number of responses given as the answer to question D3. In this case, the patient missed two doses of Pegasys. While entering data into this form, after the first date and reason are entered, the DMS will prompt for the second date and reason in the same set of boxes, which will look empty. (Note that the data already entered is not lost.) After the second date and reason are entered, the DMS will prompt for the next question.

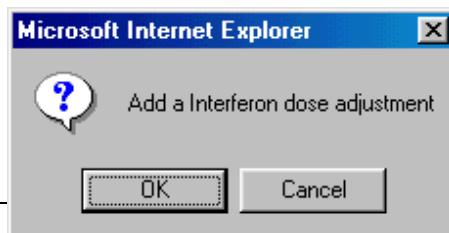
Example of a repeating segment data entry screen

The group of questions programmed as a repeating segment.

The # of the segment being entered or edited, and the total # of segments.

Repeating segment specific buttons. See below for explanation.

Some questions, on other forms, use a different mechanism to specify the number of times a segment should repeat. In those questions, a small pop-up screen asks whether to add a repeating segment.



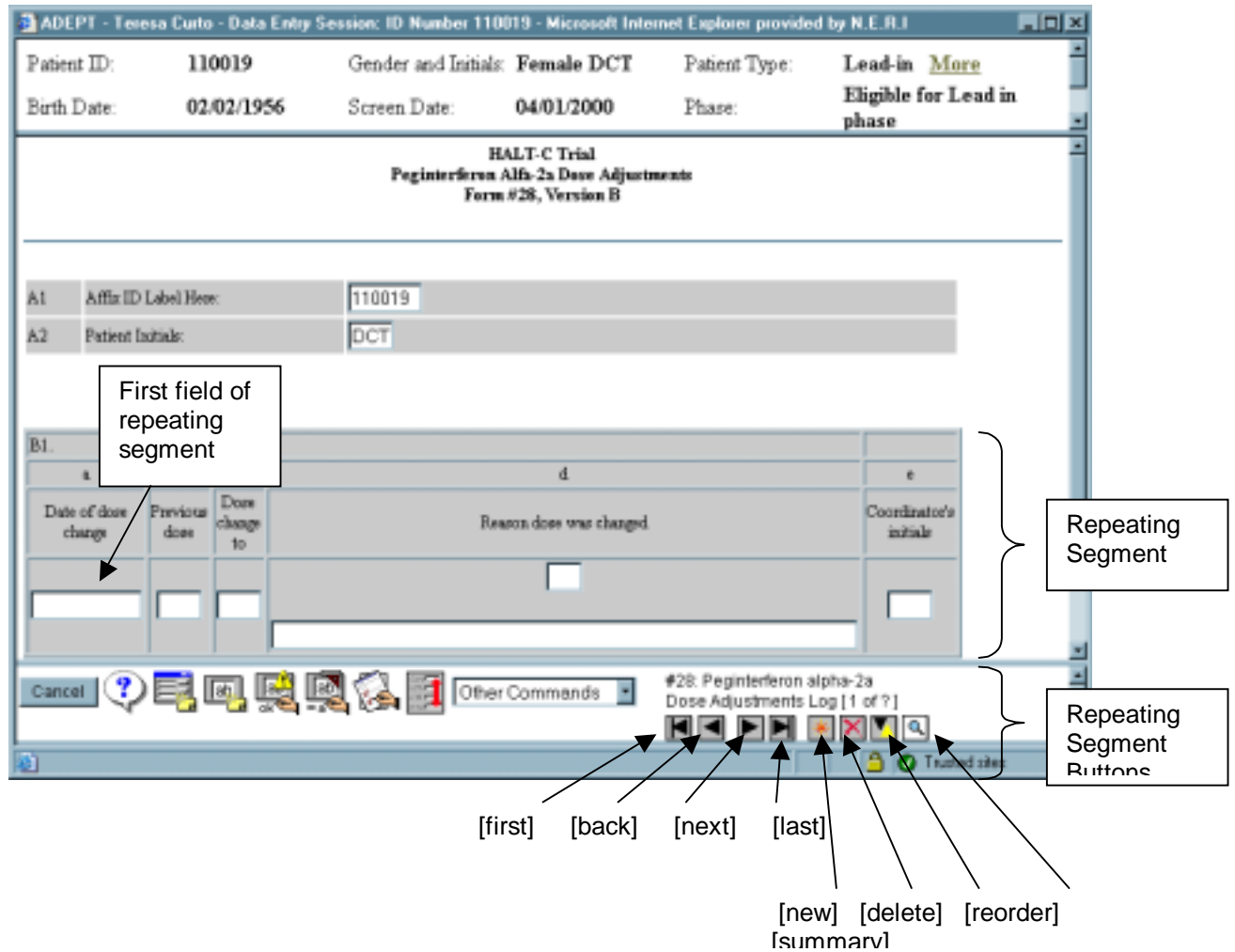
If you click on OK, you are prompted to enter the answers to the question. If you click Cancel, the DMS moves to the next question.






An example of this type of repeating segment is question C7 on Form #1, Trial ID Assignment, which asks about interferon dose adjustments during the patient's most recent treatment.

Moving around within repeating segments

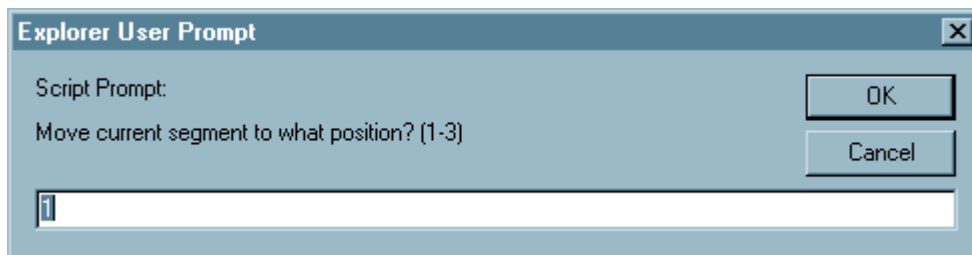
When you are in a repeating segment, all of the buttons for moving around in and manipulating repeating segments are available in the lower, right hand corner of the screen. You must be in the first field of a repeating segment to see and use the repeating segment buttons.

Repeating Segment Buttons



- Clicking the left-most button  brings you to the beginning of the first repeating segment.
- Clicking the second button from the left  brings you back one repeating segment.
- Clicking the third button  brings you to the beginning of the next repeating segment (if there is one).
- Clicking the fourth button  brings you to the beginning of the final repeating segment.
- Clicking the button shaped like a star (fifth from the left) creates a new repeating segment for data entry. The new segment will be added at the end of the current list of segments.
- Clicking the button with the red X deletes the repeating segment that is currently displayed.
- Clicking the button with 2 triangles (second from the right)  reorders the repeating segments. Once you click on the button, you will get the reorder box. Indicate the position you would like this repeating segment to be in, and click OK. All segments will automatically be reordered.

Reorder box:



- Clicking on the magnifying glass button on the far right displays the Repeating Segment summary (RS summary)
- The line of text above the buttons displays the total number of segments, and which one is currently being entered or edited. In the first example above, the message shows that the first segment of two [1 of 2] is being edited.

Repeating Segment Summary

The Repeating Segment Summary allows you to easily see all data that have been entered into all the repeating segments on the form. There are two ways to see the summary. To access it while you are in the first field of a repeating segment, click on the magnifying glass button. To see the summary at any time, select “RS Summary” from the “Other Commands” pull-down menu.

Repeating Segment Summary Example

Repeating Segment Data Form: #29: Ribavirin Dose Adjustments

ID: 110108 Visit: DRUG
Detail: (Dose changed Log: 4)

Repeating segment # 1: #29: Ribavirin Dose Adjustments Log.

Seg #	Data Status	(B1a) Date of dose change	(B1b) Previous dose	(B1c) Dose change to:	(B1d1) Reason dose change code:	(B1d2) Reason dose change description:	(B1e) Coordinator's initials
1	Saved	05/25/2001	1200	600	4		M-K
2	Saved	05/31/2001	600	0	4		M-K
3	Saved	06/07/2001	0	200	99	increase in Hgb	M-K
4	Saved	06/20/2001	200	400	99	increase in hgb	M-K

Exit

G. Go To Field

Moving around in a form can be made easier by using the “Go To Field” button, which appears at the bottom of each form data entry screen. Instead of hitting <Tab> or <Enter> until you get to the desired field, click on the “Go To Field” button. Select the question you would like to go to, and click OK. ADEPT will automatically jump to that field.

Go To Field

Select Field:

- A1 Please enter patient ID
- A2 Patient Initials
- A3 Completion Date
- A4 Initials of person completing form
- B1 Patient's Date of Birth
- B2 Patient's Gender

H. Form and Field Level Comments

If there is extra information that needs to be entered about a particular question or form, it can be entered into ADEPT using form or field level comments. Anything entered in ADEPT as a comment must also be written on the paper copy of the form (CRF). The text of the comments on the CRF should match what is entered in ADEPT.

Form Level Comment: Clicking the “form level comment” button at the bottom of the screen allows you to type in a comment that applies to an entire form. Form level comments should be used sparingly. They can be used to provide context to the entire contents of a form, e.g. if a patient was too tired to give full attention to the questions asked when an interview form was administered. Example: Form #42, Alcohol Use Questionnaire, is a patient administered form. The patient could not fill the form out herself, so you read the questions to her and wrote in the answers. Write on the CRF, “Interviewer read questions to patient and filled out questionnaire”. Enter the comment in ADEPT as a form level comment.

Field Level Comment: Clicking the “field level comment” button at the bottom of the screen while you are in a particular field allows you to type in a comment that applies to a particular question. This might be used when there is crucial information about a question that cannot be recorded as the regular response to the question. For example, if there is not enough room to record all the important information that is to go into a text field, a field level comment can be used to record the information that did not fit. As much information as possible should be entered into the regular text field. Part of the text field should say, “See comm.”, so that it is clear that there is additional information in a field level comment. Example: Form #30, Local Lab, was revised due to a change in an aberrant lab value. The change in value reflects the results of a repeat blood draw. Write on the CRF, “Blood draw 01/01/2003”. Enter the comment in ADEPT as a field level comment.

Form and Field Level Comment Window:

Enter Form Comment

Form Name: # 1: Trial ID Assignment

Comment:

Provided by: [initials]

Provided on: 09/22/2003

OK Cancel Remove Comment

Comment/Override Summary

The Comment/Override Summary allows you to easily see all field and form level comments and overrides that have been entered into the form. To see the summary, select “Comment/Override” from the “Other Commands” pull-down menu.

Comment/Override Summary Example

Comment and Override Data Form: #143: Current Cigarette Smoking - Risk Factors AS

ID: 110019 Visit M48
Detail:

Comments

Form/Field	Question # and Description	Seg#	Comments	Added By	Added Date
Field	(B1) Do you smoke cigarettes now?	1	Patient smokes 2 cigars per day.	TMC	09/09/2004

Overrides

Question # and Description	Seg#	Problem Value	Override Reason	Entered By
(A4) Visit Date	1	05/19/2002	Date confirmed with source documents	TMC

II. Log Forms

Some data forms are not expected at particular visits, and are used to record information that is ongoing, occurs between study visits, or requires regular updates. The HALT-C DMS uses log forms to enter data that are not specified for a particular study visit.

A. Three Types of Log Forms in the HALT-C DMS

1. Study medication accountability logs – tracks trial medications dispensed and returned

Form #26: Peginterferon alfa-2a Accountability Log

Form #27: Ribavirin Accountability Log

2. Dose adjustment logs – tracks changes in dose of trial medications

Form #28: Peginterferon alfa-2a Dose Adjustments

Form #29: Ribavirin Dose Adjustments

3. Adverse Event Report (Form #60) – tracks the course of a single adverse event

Use the **Category of Data** menu, at the bottom of the **Summary of ...** screens to get access to the trial medication logs, adverse event reports and clinical outcome forms. The figures on the next page illustrate this.


Data Entry Session: ID Number 200046 - Netscape

Patient ID: 200046 Gender: Male Initials: abc
 Birth Date: 10/01/1950 Screen Date: 07/20/2000 Phase: Eligible for trial
 Baseline Date: 08/01/2000 Randomization Date: // Status:

Summary of Study Visit

Description	Date	Visit Window	Forms	Expected	Pend Ed	Complete	Missing
VCS APPT Screening Visit		07/05/2000 - 08/16/2000	20	17	0	3	0
VCS APPT Baseline Visit	08/01/2000	07/20/2000 - 09/14/2000	18	17	0	1	0
VCS APPT Week 2		08/12/2000 - 08/18/2000	0	0	0	0	0
VCS APPT Week 4		08/26/2000 - 09/01/2000	0	0	0	0	0

Category of Data: Study Visit (magnifier icon)

Highlight the Study Medication Log menu item, and click on the  magnifier icon. This will bring you to the Summary of Forms for Study Medication Log screen.

Click here to enter data in this form.

ADEPT Development - Teresa Curto - Data Entry Session: ID Number 200046 - Microsoft Internet Explorer

Patient ID: 200046 Gender and Initials: Male abc Patient Type: Lead-in [More](#)
 Birth Date: 10/01/1950 Screen Date: 07/20/2000 Phase: Eligible for Lead in phase
 Enrollment Date: 08/01/2000 Randomization: Status: Unwilling/Ineligible

Summary of Forms for Study Medication Log

Description	Form Status
#26: Peginterferon alfa-2a Accountability Log (Dispensed Log: 2 /Returned Log: 1)	Expected
#27: Ribavirin Accountability Log	Expected
#28: Peginterferon alfa-2a Dose Adjustments	Expected
#29: Ribavirin Dose Adjustments	Expected

Category of Data: Study Medication Log (magnifier icon)

From this screen, use the Category of Data menu and click on the magnifier to return to the Summary of Study Visit screen, or to move to the summary screens for Adverse Event or Clinical Outcomes.

B. Data Entering Log Forms

To enter data into one of the log forms, click on the green, Enter Data button. An example of the data entry screen for Form #26, Peginterferon alfa-2a Accountability Log, appears below.

After Section A, which is entered once for each form, all of the log forms are programmed so that data is entered into a repeating segment. Data from one row of the log form is entered into one repeating segment.

The screen shot below shows the data entry screen while entering the first log entry. This is for the initial dose of Peginterferon alfa-2a given at the baseline visit (W00), to patient ABC.

HALT-C Trial
Peginterferon alfa-2a Accountability Log
Form #26

A1	Affix ID label here:	200046
A2	Patient initials:	ABC

Note: Peginterferon alfa-2a must be stored refrigerated at 2-8 C

B1. Initial dose of Peginterferon alfa-2a:

Peginterferon alfa-2a Dispensed			
a	b	c	d
Dosage	Date Dispensed	# Vials Dispensed	Batch #
<input type="text" value="1"/>	<input type="text" value="08/01/2000"/>	<input type="text" value="4"/>	<input type="text" value="197139"/>

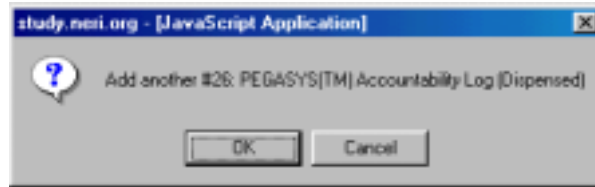
Other Commands

#26: Peginterferon alpha-2a Accountability Log (Dispensed) [1 of 1]

Note that since this is programmed as a repeating segment, all of the buttons for moving around in and manipulating repeating segments are available in the lower, right hand corner of the screen. See Section F for more information on repeating segments.

After entering B2d and hitting <Enter> or <Tab>, a box is displayed. This box gives the option of adding another repeating segment for the Dispensed part of the Peginterferon alfa-2a Accountability Log.

Click the “OK” button if there is another line of data to enter at this time. If not, click “Cancel”.



After clicking on “Cancel” another box is displayed, which gives the option of adding a repeating segment entry for the Returned part of the Peginterferon alfa-2a Accountability Log.



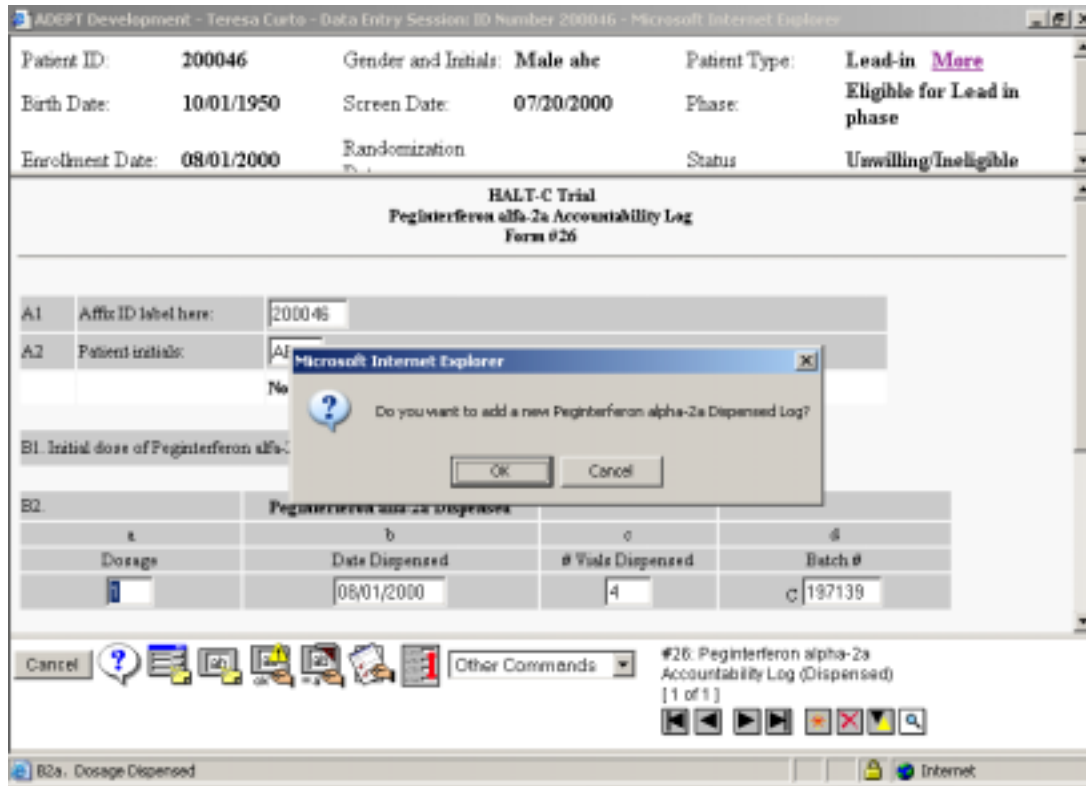
If there are no Returned entries to data enter, you would click “Cancel”. Since this is the end of the form, it is “added”, and you are returned to the “Summary of Forms for Study Medication Log” screen. This screen now shows that 1 Dispensed log entry has been entered, and 0 Returned log entries have been entered for Form #26, Peginterferon alfa-2a Accountability Log.



Now that data entry of the first line of data is complete, this should be noted (in black ink) on the gray “D/E” column of the paper form, and the form should be returned to patient ABC’s binder.

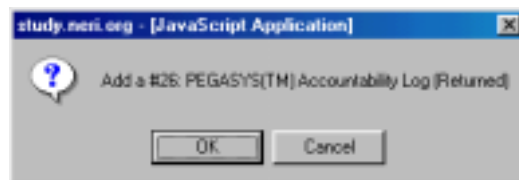
In our example, patient ABC returns the empty vials at the week 4 (W04) visit, and is given 4 more vials of Peginterferon alfa-2a.

To enter the additional log entries, click on the green “Enter Data” button to return to the data entry screen for the Peginterferon alfa-2a Accountability Log. Tab through Section A and question B1. When you reach question B2, a box is displayed, which asks. “Do you want to add a new Peginterferon alfa-2a Dispensed Log?”



If you click “OK”, your cursor will move to B2a for a new log entry (repeating segment). The message at the bottom of the screen will display that you are entering data into “#26: Peginterferon alfa-2a Accountability Log (Dispensed) 2 of 2”.

This time, at the end of the repeating segment (after B2b), answer “OK” when asked if you want to add a Returned entry.



After adding the Returned entry, the Summary of Forms for Study Medication Log screen will show that 2 Dispensed log entries and 1 Returned log entry have been entered for form #26, Peginterferon alfa-2a Accountability Log.

III. Scheduling Appointments in the DMS

Clicking on the APPT button on the Summary of Study Visit screen moves you into the optional appointment-scheduling portion in the DMS.



Once there, you can schedule new appointments by clicking on the Create New Appointment button.



The Add New Appointment screen will be displayed. Options on this screen allow you to choose an appointment type (Study Visit, Ultrasound Visit, Biopsy Visit, Endoscopy Visit, and some special visits for Ancillary Studies), and set the date and time of the visit. Text can be added to the optional Staff, Location and Comments fields.



When you are satisfied with the appointment, click the Save button.

You will be returned to the Scheduling Appointments screen, where all appointments that have been scheduled for this patient at this visit are displayed. To print the list of appointments, click the printer icon in the upper right hand corner of this screen.

