HALT-C Data Management System Reports

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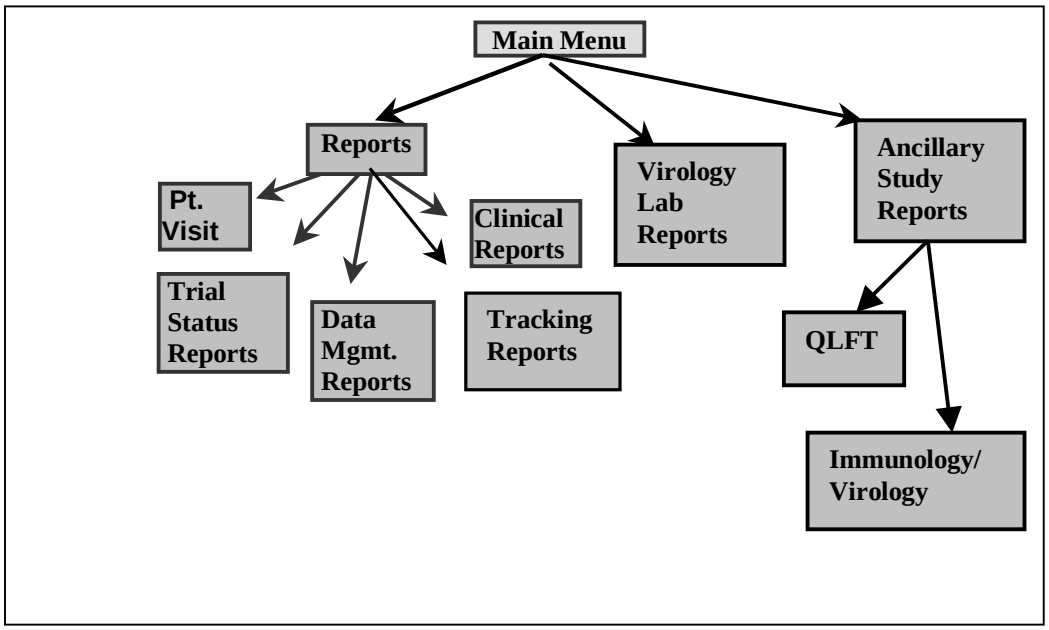
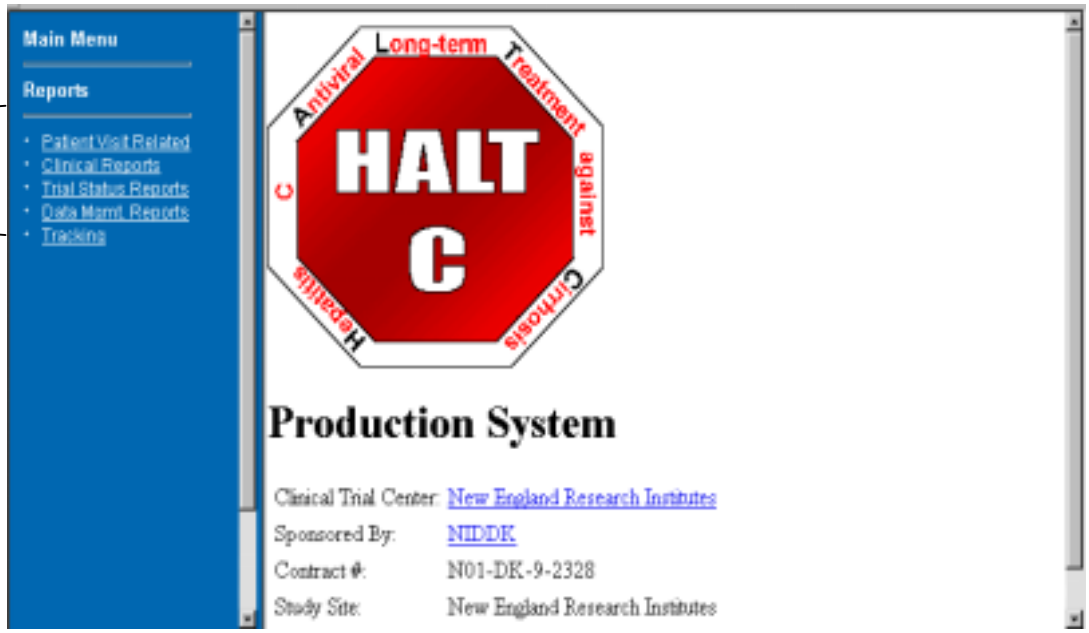
I. Introduction



Site reports related to the HALT-C Main Trial are run from the Reports portion of the Data Management System (DMS) as one of the options on the Main Menu. Under **Reports**, there are five sub-menus, each of which contains a list of reports that can be run in the DMS:

- Patient Visit Related Reports
- Clinical Reports
- Trial Status Reports
- Data Management Reports
- Tracking Reports

Click on the type of report you would like to run, and the list of reports you can run will be displayed.

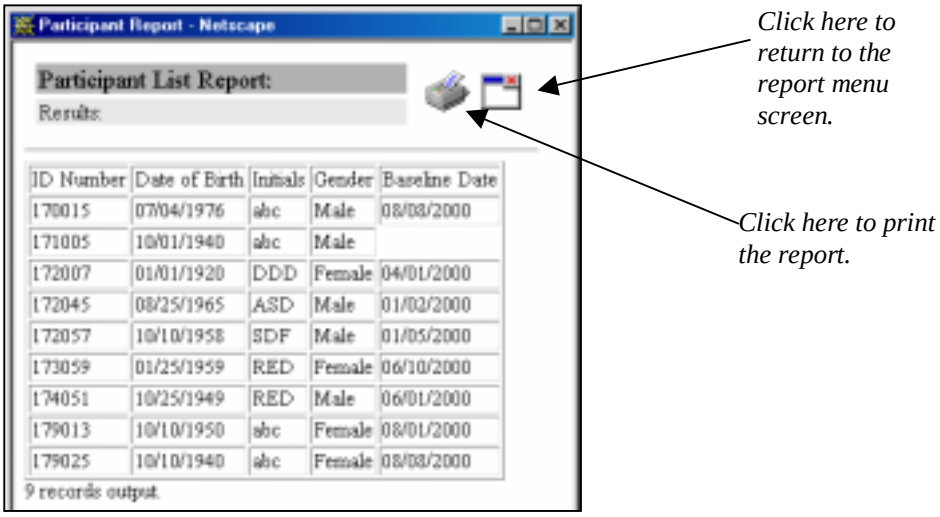


Each of these types of reports will be discussed below. Additional reports will be developed as needed during the trial.

Virology Lab reports related to the Main Trial are run from the **Virology Lab Reports** submenu item.

Reports related to the Immunology/Virology or QLFT Ancillary studies are available from the **AS Reports** submenu item. Note that you will be able to see these reports only if your clinical center participates in these Ancillary Studies.

At the top of each report, there are icons for both printing the report and exiting the report (returning to the report menu screen).



<u>Please note</u> - Unless otherwise indicated, the data these reports display, in this section, are all based on data entry during training and development. They are not based on actual patient data. Where real patient data are used, identifying information is blacked out.

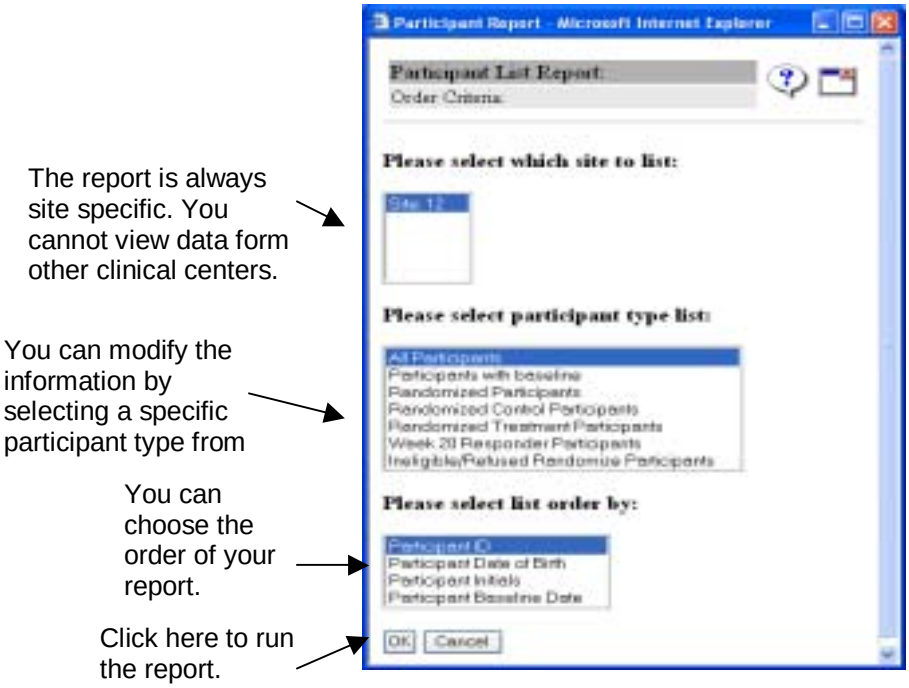
II. Reports

A. Patient Visit Related Reports

The Patient Visit Related reports display information about patient visits. The following reports are available under Main Menu – Reports - Patient Visit Related. Each of the reports will be listed below with a brief explanation.

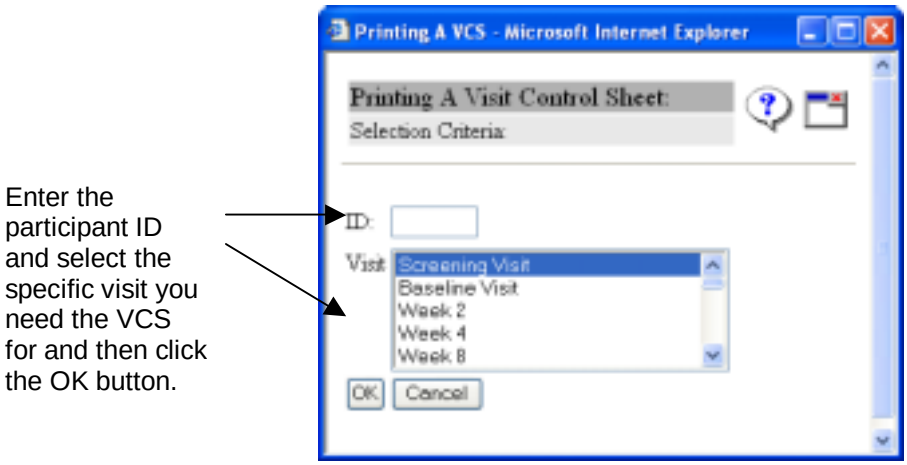
- **Participant List:**

Displays a list of participants at each center, including patient ID, initials, date of birth, gender, baseline date, randomization date and status.



- **Print a VCS:**

Allows users to print out Visit Control Sheet (VCS) for a patient on a specific study visit. Note: A VCS can also be printed from the Summary of Study Visit Screen, under the Patient Data Entry menu item. See sections C.1 and C.3 of this manual for more information on Visit Control Sheets.



- **Participant Status List:**

Displays the current trial status of each patient at a given site. For each patient, this report also displays relevant trial-related dates, such as the trial ID assignment date, baseline date, and randomized date. Please be patient when running this report, since it may take a few moments to retrieve all the data from the database.

- **Participant Visit Windows**:

Allows the user to view visit windows for each visit for a particular patient. After entering a patient ID, the report displays the window dates for each patient visit, and the appointment date and time, if an appointment has been schedule in ADEPT.

- **Visits Without Appointments**:

By selecting a date range, this report lists out all patient IDs that have completed a patient visit where an appointment was not scheduled in the ADEPT system. You can sort the information by Patient ID, or Window Start Date, or Patient ID, Window Start Date.

- **Appointment List:**

This report lists appointments that have been entered into the system. The DE user must supply a date range. Optional selection criteria include study visit and appointment types. Output can be sorted by a number of options. The open text fields of staff, location and comments can be checked (included) or unchecked (excluded).

- **Randomized Responders:**

This is not a report, but a special menu item, which allows users to randomize a patient with a W20 Responder status if they meet all the given criteria. This program is used to start the randomization process for responders who had 2 HCV-RNA positive results in visit W36, W48, W60 or W72. The program will check to make sure responders have 2 positive HCV-RNA results and, if eligible, an expectation of the Randomization Checklist will be added to the latest positive HCV result visit. Please call the DCC prior to using this feature for the first time.

- **Randomization Status:**

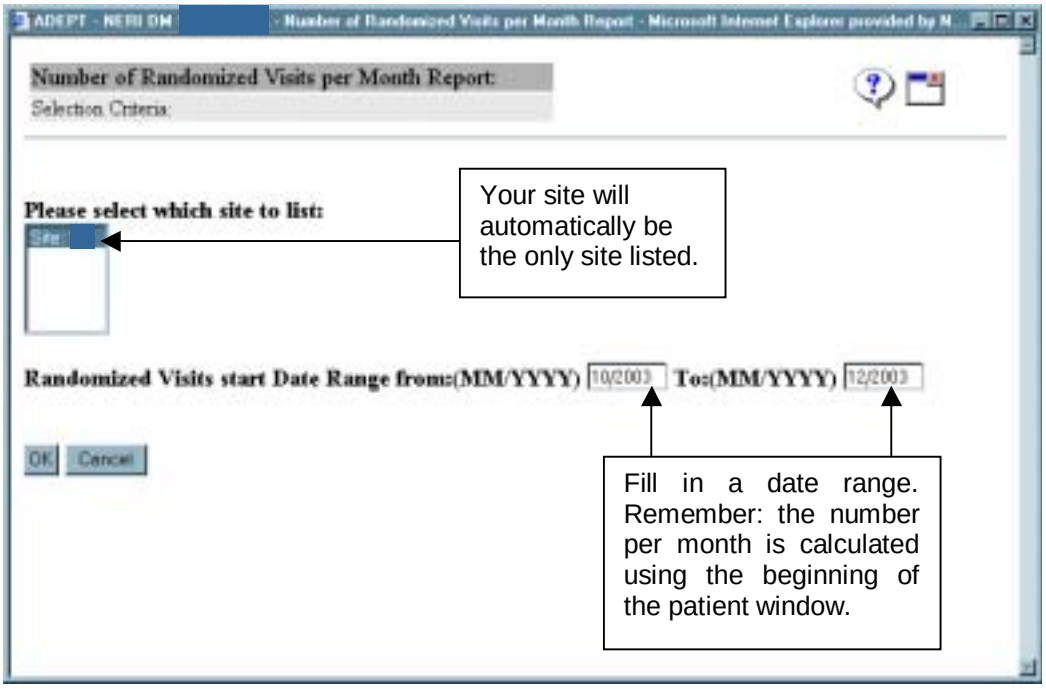
This report provides source documentation of patient randomization status for the DCC and Clinical Centers. This report lists patient randomization status based upon your selection. You can either enter a particular participant ID or the whole site and you can select the data by Patient ID, Patient Initials, Patient Type, Randomization Date, or Randomization Result.

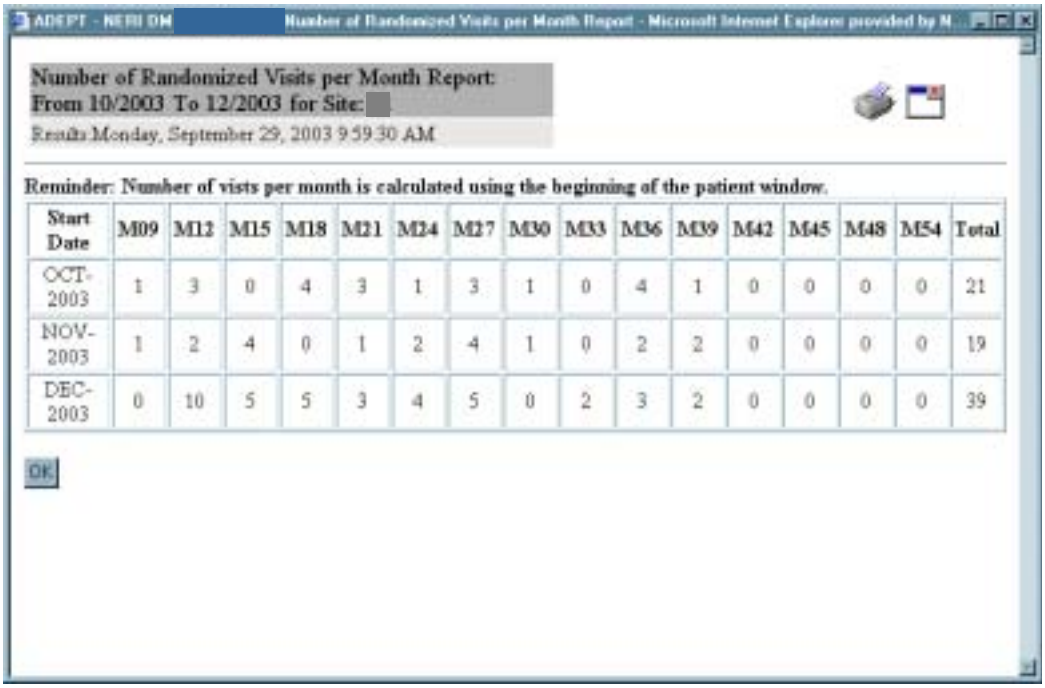
- **Most Recent Visit:**

This report lists the most recent visit date for each ID based upon your selection. You can sort the report by Patient ID, Visit, or Visit Date.

- **Number of Randomized Visits per Month:**

This report lists all randomized visits in each month based upon your data range. The number of visits is calculated using the beginning of the visit window. This report gives you information about the **future**. It is used for **planning.** A sample report is given below.





Start Date	M09	M12	M15	M18	M21	M24	M27	M30	M33	M36	M39	M42	M45	M48	M54	Total
OCT-2003	1	3	0	4	3	1	3	1	0	4	1	0	0	0	0	21
NOV-2003	1	2	4	0	1	2	4	1	0	2	2	0	0	0	0	19
DEC-2003	0	10	5	5	3	4	5	0	2	3	2	0	0	0	0	39

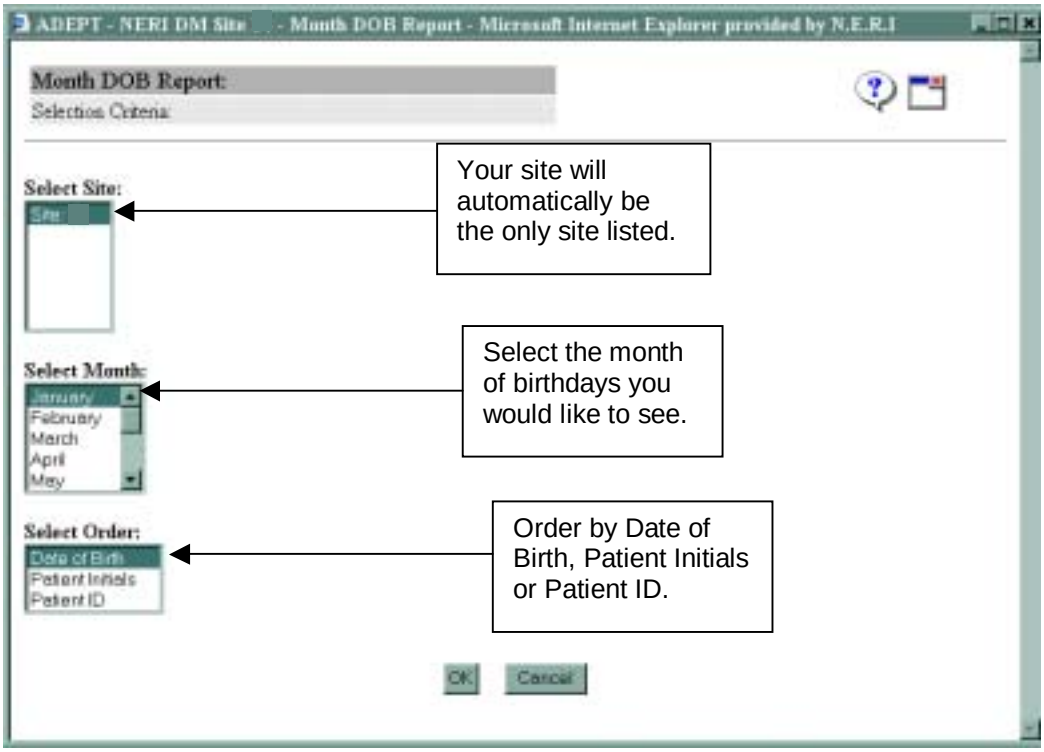
- **Detailed Randomize Visits**:

This report lists all randomized visits **in detail** based upon your data range. A sample report is given below.

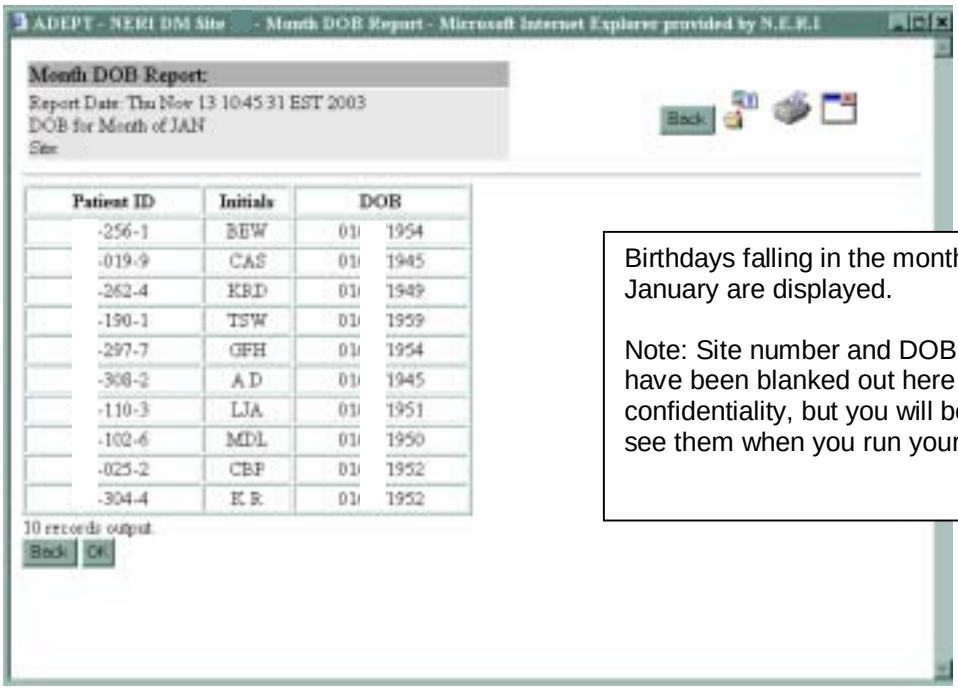
Patient ID	Patient Initial	Visit	Visit Window	Visit Date	Appt Date	Appt Time	Staff	Location	Comments
11-915-6/MA	RAS	M21	01/01/2003-03/01/2003						
11-915-6/MA	RAS	M45	01/01/2003-12/01/2003						
11-915-6/MA	RAS	M54	01/01/2003-12/01/2003						

- **Monthly DOB Report:**

This report lists active HALT-C participant date of birth (DOB), Patient ID, and Patient Initials based upon your selection of a particular month. You can modify the data by sorting it by Patient Initials, ID, or date of birth. You can use this report to find out which patients will have birthdays next month so you can send out birthday cards.



You will see a list of patient birthdays for the month selected.



Birthdays falling in the month of January are displayed.

Note: Site number and DOB day have been blanked out here for confidentiality, but you will be able to see them when you run your report!!

- **Upcoming Procedures Report:**

Please note that this report is *not* a comprehensive list of all upcoming procedures. Refer to the Visit Control Sheet (VCS) for the complete schedule of procedures. The intent of this report is to list procedures that take more time or require extra scheduling. The report is a useful tool for planning your month.

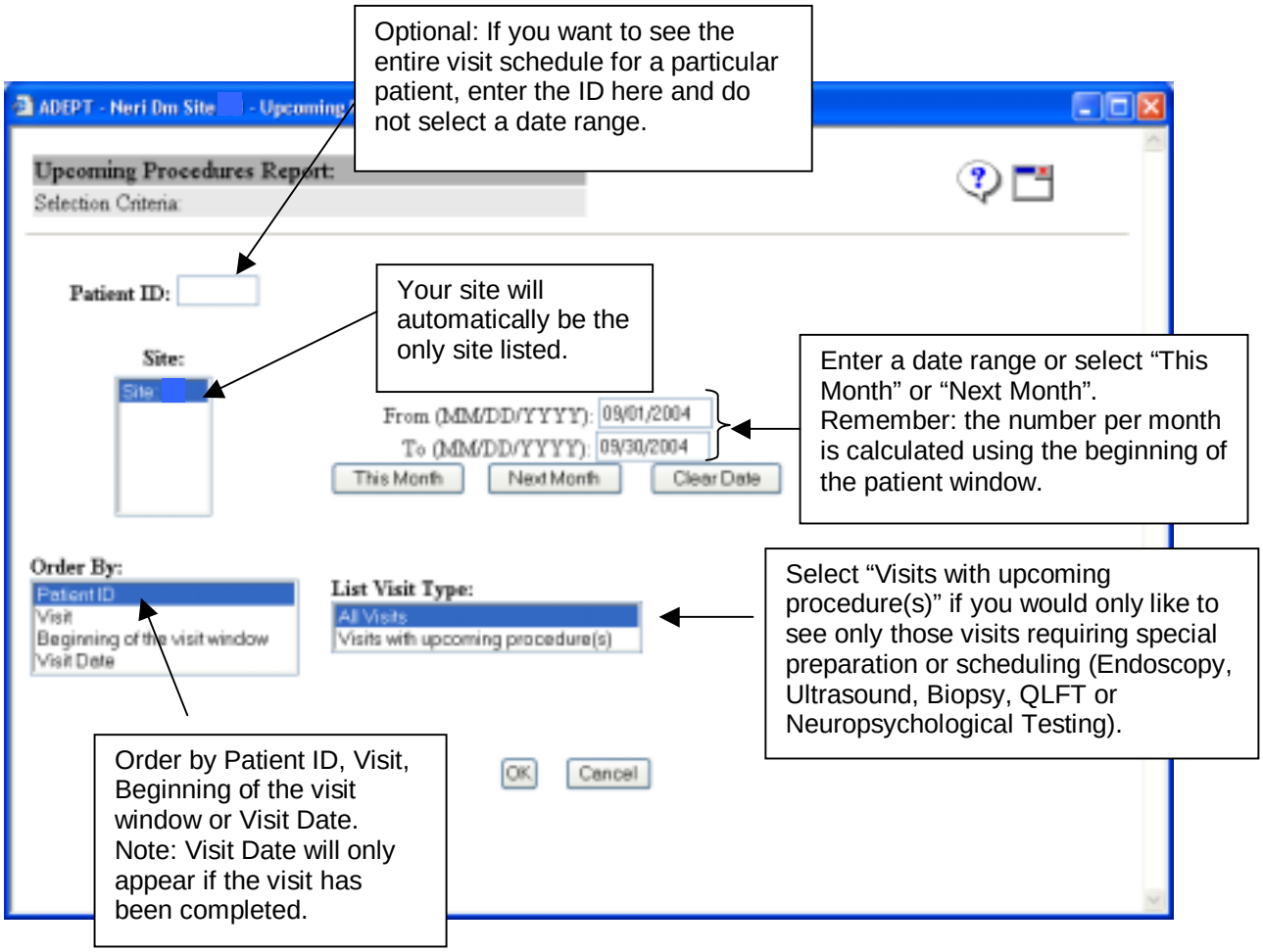
The procedures included in the report are:

a. Endoscopy
b. Ultrasound
c. Biopsy (with specific requirements, depending on the Ancillary Study)
d. QLFT (for those participating in the QLFT Ancillary Study)
e. Neuropsychological Testing (for those participating in the Cognitive Effects Ancillary Study)
f. Fresh Blood shipping for PBMC

The report gives information about:

a. Visits due in the time period selected.
b. Special procedures (those taking more time; needing extra scheduling) that need to be performed for each patient.
c. Ancillary Study procedures (those taking more time; needing extra scheduling) that need to be performed for each patient.
d. Totals for each procedure needing to be performed in the time period selected.

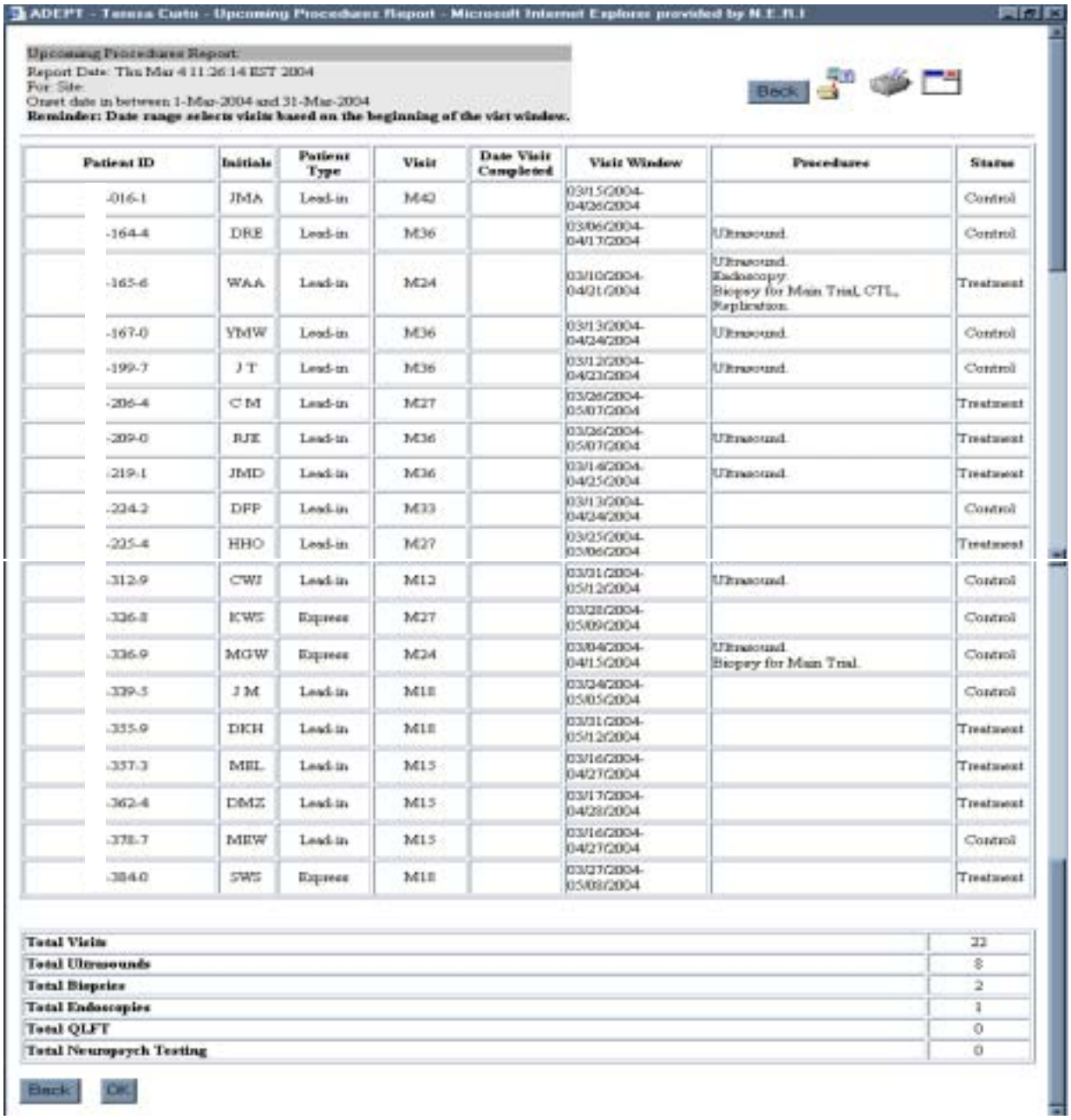
To access the report, go to Reports-Patient Visit Related. You will see the following screen:



Here is what the report looks like. At the top, you will see all of the criteria you selected for the report. Then you will see a list of patients and the procedures due. Totals are at the bottom of the screen.

Remember: the number per month is calculated using the beginning of the patient window.

Note: "Biopsy for Main Trial" will be listed for all patients requiring a biopsy. If there are additional procedures required for that biopsy, due to participation in an Ancillary Study, more information will be listed after "Biopsy for Main Trial", such as "Biopsy for Main Trial, TGF-B1" or "Biopsy for Main Trial, Iron (HIC), CTL, Replication".



ADEPT - Teresa Cuetu - Upcoming Procedures Report - Microsoft Internet Explorer provided by N.E.R.I

Upcoming Procedures Report:
Report Date: Thu Mar 4 11:26:14 EST 2004
For: Site:
Onset date in between 1-Mar-2004 and 31-Mar-2004
Reminder: Date range selects visits based on the beginning of the visit window.

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Patient ID	Initials	Patient Type	Visit	Date Visit Completed	Visit Window	Procedures	Status
-016-1	JMA	Lead-in	M42		03/15/2004-04/26/2004		Control
-164-4	DRE	Lead-in	M36		03/06/2004-04/17/2004	Ultrasound.	Control
-165-6	WAA	Lead-in	M24		03/10/2004-04/21/2004	Ultrasound. Endoscopy. Biopsy for Main Trial, CTL, Exploration.	Treatment
-167-0	YMW	Lead-in	M36		03/13/2004-04/24/2004	Ultrasound.	Control
-199-7	J T	Lead-in	M36		03/12/2004-04/23/2004	Ultrasound.	Control
-206-4	C M	Lead-in	M27		03/26/2004-05/07/2004		Treatment
-209-0	RJE	Lead-in	M36		03/26/2004-05/07/2004	Ultrasound.	Treatment
-219-1	JMD	Lead-in	M36		03/14/2004-04/25/2004	Ultrasound.	Treatment
-224-2	DPP	Lead-in	M33		03/13/2004-04/24/2004		Control
-225-4	HHO	Lead-in	M27		03/25/2004-05/06/2004		Treatment
-312-9	CWI	Lead-in	M12		03/31/2004-05/12/2004	Ultrasound.	Control
-326-8	KWS	Express	M27		03/28/2004-05/09/2004		Control
-336-9	MGW	Express	M24		03/04/2004-04/15/2004	Ultrasound. Biopsy for Main Trial.	Control
-339-3	J M	Lead-in	M18		03/24/2004-05/05/2004		Control
-355-9	DKH	Lead-in	M18		03/31/2004-05/12/2004		Treatment
-357-3	MEL	Lead-in	M15		03/16/2004-04/27/2004		Treatment
-362-4	DMZ	Lead-in	M15		03/17/2004-04/28/2004		Treatment
-378-7	MEW	Lead-in	M15		03/16/2004-04/27/2004		Control
-384-0	SWS	Express	M18		03/27/2004-05/08/2004		Treatment

Total Visits	22
Total Ultrasounds	8
Total Biopsies	2
Total Endoscopies	1
Total QLFT	0
Total Neuropsych Testing	0

Back OK

- **Visit Data Cleaning:**

The report combines the following reports in one single document: Site Pending Edits, Site Outstanding Forms, Block Tracking, Does Adjustment reports, Dispense/Return reports, SAE & AE reports. Before this report was created, if you wanted to do any individualized data cleaning as patients came in for their visits, you had to run each report separately. Then you would have to go through and find which items applied to your patient. Now, you simply enter the ID number for the patient coming in for a visit. All of the above reports are automatically run for you, but only for that single ID number. Once you have printed the report, keep it with the visit control sheet and the rest of the patient packet.

To cut down on time and future data cleaning, generate the report before each patient visit. If you see that a form or Block Food Questionnaire is outstanding, you can add that form to the patient's packet. If a form is pending edits, you can resolve the edit while the patient is in the clinic for his or her visit. The report also gives you patient-specific information about medications, adverse events and serious adverse events, which you may be able to resolve while the patient is in the clinic.

This is also a useful report to run when a patient will be transferring to another site or needs to be terminated. Run the report to see what is still needed before proceeding with transfers or terminations.

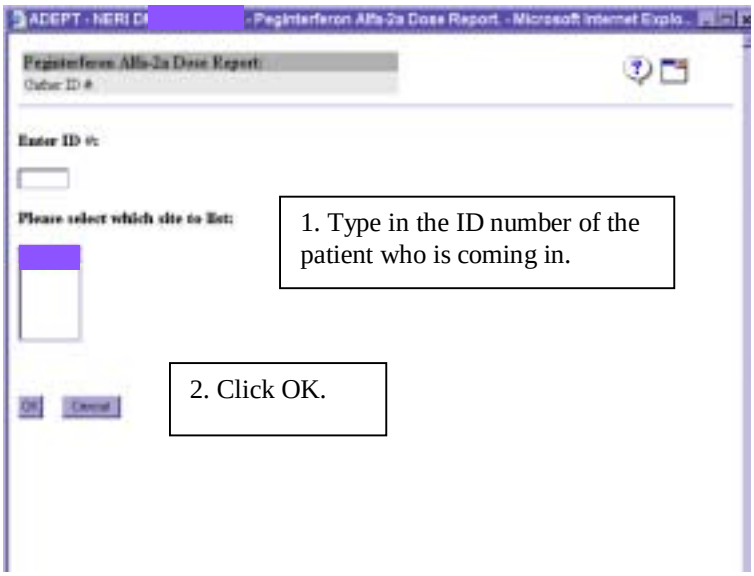
B. Clinical Reports

These reports display clinical information on patients, extracted from data in the HALT-C DMS. This menu item consists of seven submenu items to better direct the user when accessing clinical reports. Reports available are:

1. Trial Meds:

- **Peginterferon Doses:** Reports any dose changes and reason(s) for a specified patient. You can run the report by entering a valid Patient ID number.
- **Ribavirin Doses:** Reports any dose changes and reason(s) for a specified patient.

The Peginterferon Dose Report can be run by patient or for the whole site. (The Ribavirin Dose Report is run the exact same way and the same instructions apply.)



The report displays all dose adjustments entered into the DMS. The report should be checked against the hard copy in the patient's chart to ensure that all entries have been data entered and match. *Please do not use "99-Other" as a reason if one of the other options is better suited*.

Be sure that the "Previous Dose" of the most recent entry (01/07/2001) corresponds to the "New Dose" of the previous entry (12/17/2000). Please see highlighted doses below as an example.

Once a patient has been randomized to treatment, both medications should be dose adjusted, peginterferon to "90", unless otherwise indicated by the PI, and ribavirin to "0". When a patient is randomized to control, both peginterferon and ribavirin should be dose adjusted to "0".

Peginterferon Alfa-2a Dose Report for Site: XX

Report Date: Tuesday, March 09, 2004 3:21:08 PM

Patient ID #: XX0552 **Patient Initials: XXX** **Date of initial interferon dose: 11/13/2000** **Initial dose: 180 mg**

Date	Previous Dose	New Dose	Reason for Dose Change	Explanation
11/13/2000		180 mg		
12/17/2000	180 mg	**135 mg**	Adverse reaction	absolute NE0.7
01/07/2001	**135 mg**	180 mg	Adverse event resolved	Absolute NE up 1.0
10/07/2001	180 mg	0 mg	Changed according to protocol	

- **Peginterferon Dispense/Return List:**

Reports Interferon dispensation and return information for each patient. The report displays all Peginterferon dispensations and returns entered into the DMS. The report should be checked against the hard copy of Form #26 in the patient's chart to ensure that all entries have been data entered and match.

Once a patient has been randomized and they have brought in all 180 ml vials of drug that they have, all unaccounted for 180 ml vials of peginterferon should be declared "lost" and should be recorded on Form #926 Lost Drug Accountability Log. Please refer to the QxQ if you need more explicit instructions for completing the form.

- **Ribavirin Dispense/Return List:**

Reports Ribavirin dispensation and return information for each patient. The report displays all Ribavirin dispensations and returns entered into the DMS. The report should be checked against the hard copy of Form #27 in the patient's chart to ensure that all entries have been data entered and match.

2. AEs

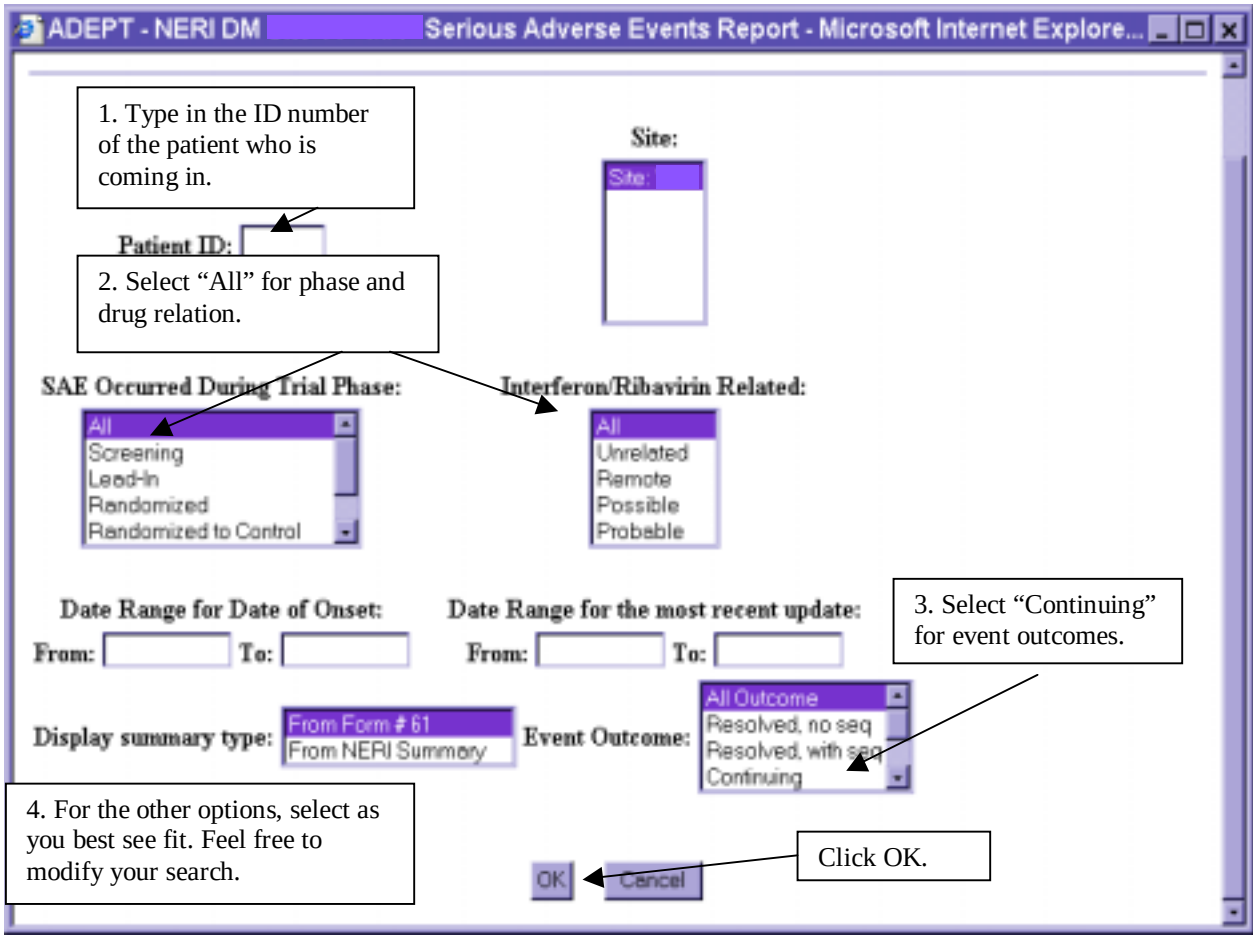
- **Serious Adverse Events:**

Displays a detailed list of all SAE's data entered for your site. To run the report enter a valid Patient ID number (optional) and then modify your search. You can search for SAEs that occurred during a specific trial phase, or you can select a date range for date of onset or for a more recent update. You can also modify the selection by searching for a Peginterferon/Ribavirin related event or for a specific event status.

This report will generate a list for that particular patient indicating any SAEs that are still listed as continuing in the DMS. The report should be checked against the hard copies in the patient's chart to ensure that all entries have been data entered and match.

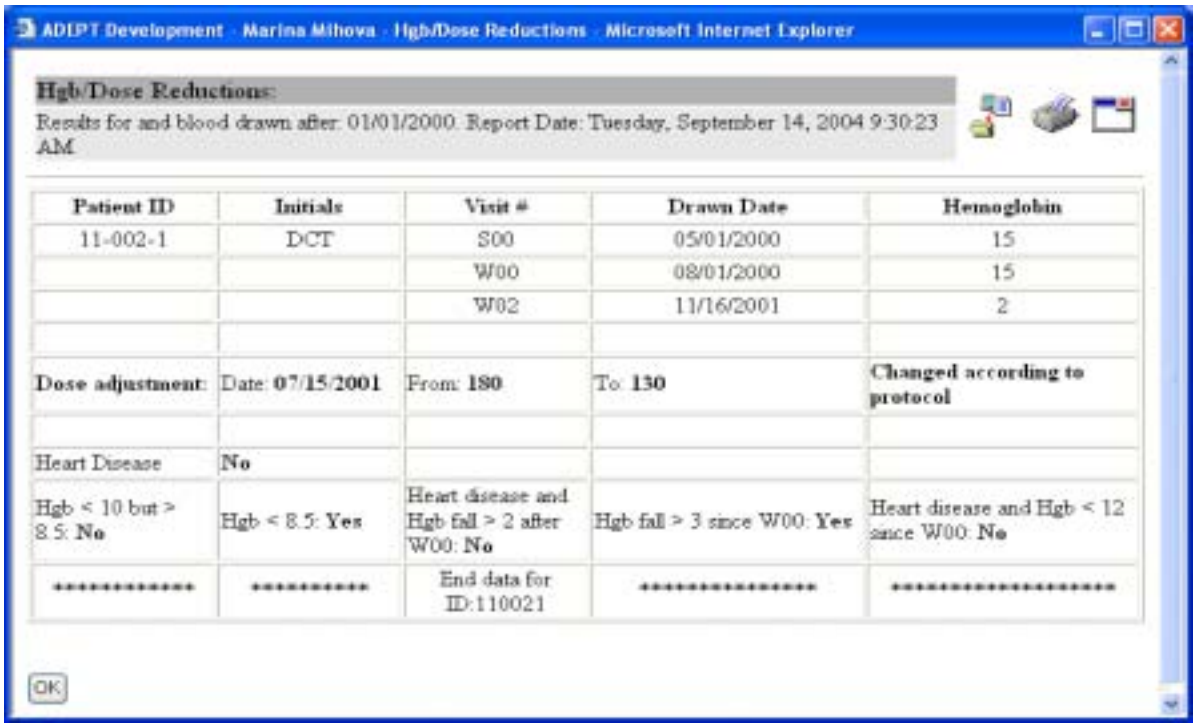
Any SAE that has been continuing for longer than three months should be followed up on and an update should be completed.

This report will also let you know what the ICD-9 code entered was and this code should be checked to *make sure that 799.9 is not displayed*. If so, change to the appropriate code. If you need assistance contact NERI.



- **Hgb/ Dose Reduction:**

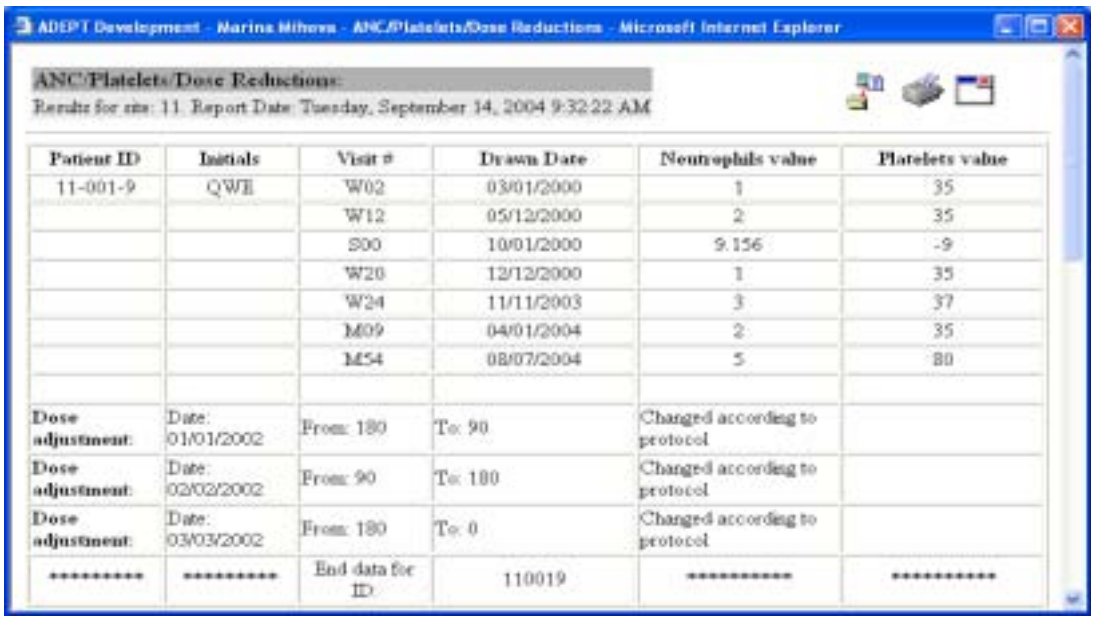
Reports all dose reduction related to low hemoglobin. You can search for hemoglobin dose reductions after a specific date. The report lists Patient ID, Initials, Visit #, Draw Date, and Hemoglobin. Any dose adjustments are also listed with respective reasons. The presence or absence of heart disease is marked at the end of the report for each Patient ID.



Patient ID	Initials	Visit #	Drawn Date	Hemoglobin
11-002-1	DCT	S00	05/01/2000	15
		W00	08/01/2000	15
		W02	11/16/2001	2
Dose adjustment:	Date: **07/15/2001**	From: **180**	To: **130**	**Changed according to protocol**
Heart Disease	**No**			
Hgb < 10 but > 8.5: **No**	Hgb < 8.5: **Yes**	Heart disease and Hgb fall > 2 after W00: **No**	Hgb fall > 3 since W00: **Yes**	Heart disease and Hgb < 12 since W00: **No**
**********	**********	End data for ID:110021	**********	**********

- **ANC/Platelets/Dose Reductions:**

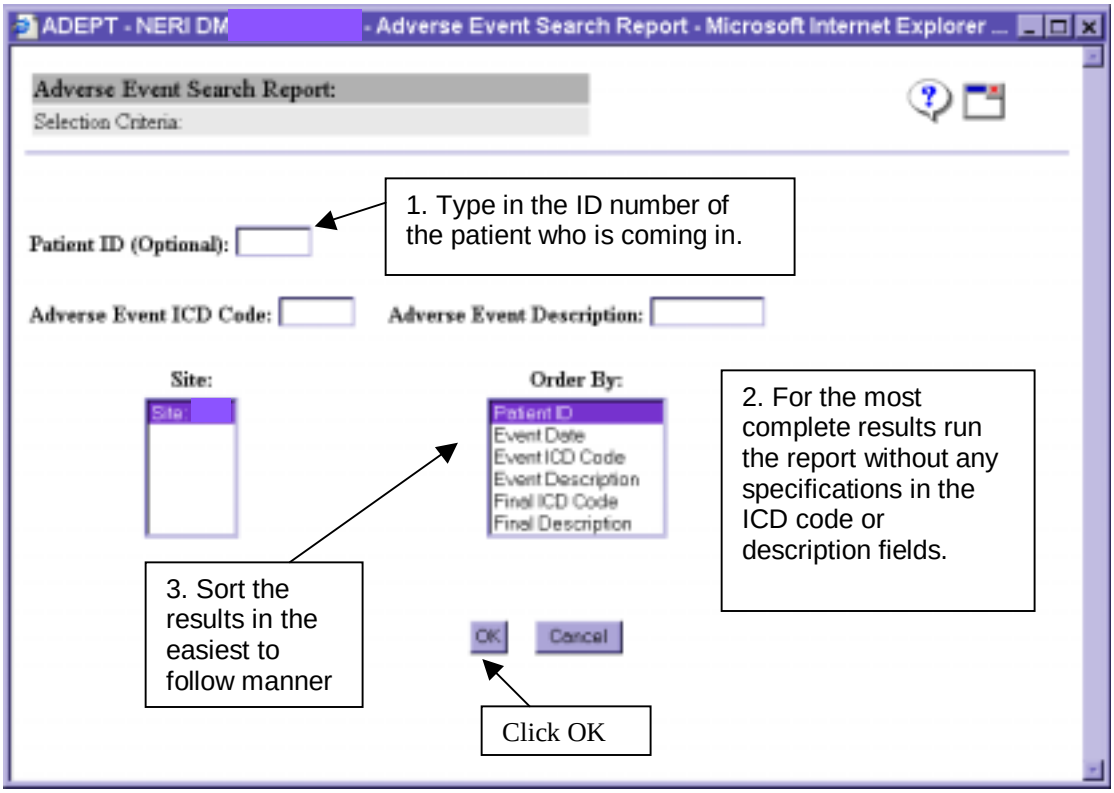
Reports all dose reductions related to low ANC and Platelets.



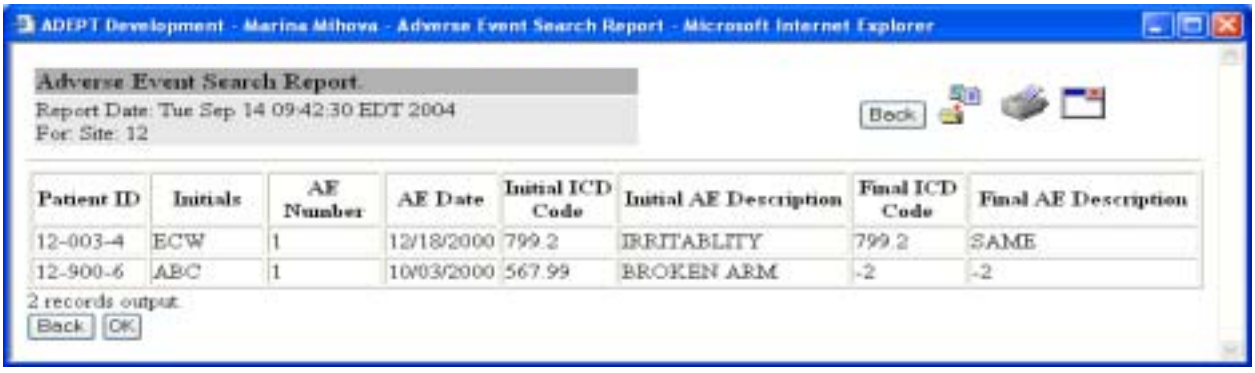
Patient ID	Initials	Visit #	Drawn Date	Neutrophils value	Platelets value
11-001-9	QWE	W02	03/01/2000	1	35
		W12	05/12/2000	2	35
		S00	10/01/2000	9.156	-9
		W20	12/12/2000	1	35
		W24	11/11/2003	3	37
		M09	04/01/2004	2	35
		M54	08/07/2004	5	80
Dose adjustment:	Date: 01/01/2002	From: 180	To: 90	Changed according to protocol	
Dose adjustment:	Date: 02/02/2002	From: 90	To: 180	Changed according to protocol	
Dose adjustment:	Date: 03/03/2002	From: 180	To: 0	Changed according to protocol	
**********	**********	End data for ID	110019	**********	**********

- **AE Searching:**

This report allows you to search for a specific AE. You can set up specific selection criteria to modify the search.



The report displays all adverse events entered into the DMS. The report should be checked against the hard copy in the patient's chart to ensure that all entries have been data entered and match.
The code of 799.9 is not an acceptable code. If coding assistance is needed please contact the DCC.
Adverse events that are continuing are indicated by a "-2" in the Final ICD Code and description columns. These should be followed up on at the visit to ensure timely resolution of these events.
This report may also be helpful when trying to determine and ICD-9 code for a particular event. Try using different key words in the Adverse Event Description box and see what you come up with.



3. Labs

- **Cumulative Lab Report:** Displays lab results that have been recorded in the DMS for a patient
- **AFP Report:** Reports the AFP results for a patient and the visit
- **HCV RNA Report:** Displays HCV RNA results for a patient at a chosen study visit
- **Aberrant Lab Value:** Displays out-of-range values for each patient and the clinical center
- **Genotype Report:** Displays the genotype of the HCV RNA for a chosen patient

4. Ishak Scores

- **Ishak Scores:** The report lists all the Ishak scores at your clinical center.
- **Individual Ishak Scores:** The report lists individual Ishak scores for the Patient ID you have entered.

5. Clinical Outcome

- **Clinical Outcome Report:**

The report lists all clinical outcomes in order of ID and adverse event number for your clinical center. You can modify your search by looking at a specific type of outcome, time period, or trial phase. You may also choose to run the report for a specific patient ID. The report gives detailed information about each outcome including patient information, description and decisions.

- **Clinical Outcome Summary:**

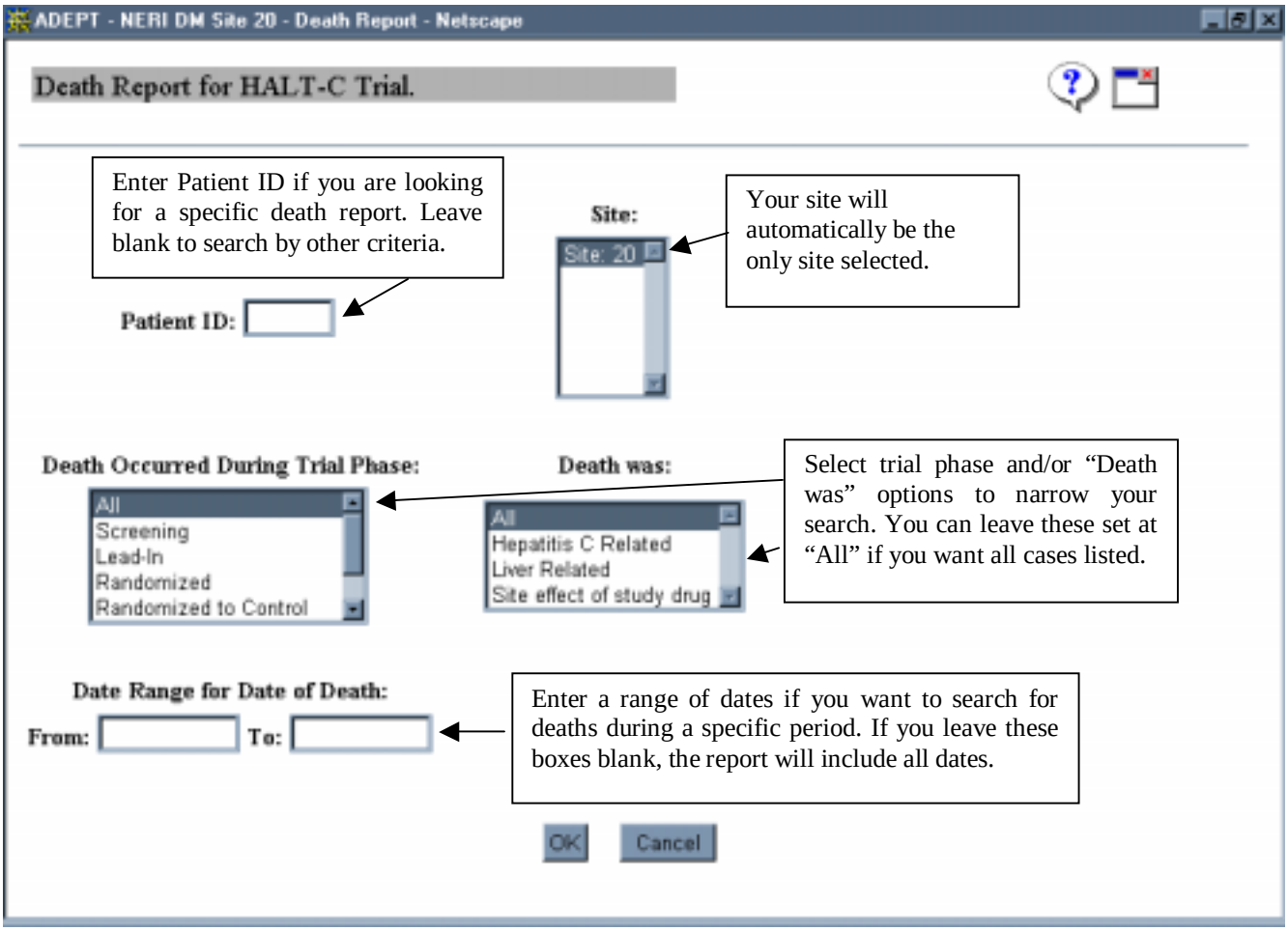
The report lists all clinical outcomes and adverse event number for your clinical center. You can modify your search by looking at a specific type of outcome or time period. You may also choose to run the report for a specific patient ID. The report gives a single line of information about each outcome.

6. Medications Report:

The report lists all medications. You can search for all medications, prescription drugs only, or OTC/Herbal medications only. It can be run for the whole clinical center or for a specific patient ID or medication code. You can sort the information by patient ID, medication code, or reported start date.

7. Death Report:

The Death Report is a summary of the Death Report (Form # 64). This report is sent to the Data Safety Monitoring Board (DSMB) as deaths occur and in included in the annual DSMB report. The report includes a quick summary of the death including the date, whether the patient was admitted to the hospital, if there is an autopsy report available, whether the death is related to hepatitis C, liver, or study drug, and a summary by the site's PI of the patient's death. When using the report you can modify your search my entering a particular Patient ID, date range, trial phase, or cause of death.



C. Trial Status Reports

- **Trial Status Report:**

Displays a "snapshot" of the current trial status of patients at your site. It displays the number (and %) of patients at different points of the screening process and at each of the trial phases.

- **Trial Status by Race:**

Similar to the Trial Status Report, except that this report displays a breakdown of patients by race.

- **Trial Status by Gender:**

Also similar to the Trial Status Report, but this report displays a breakdown of patients by gender.

- **Monthly Recruitment:**

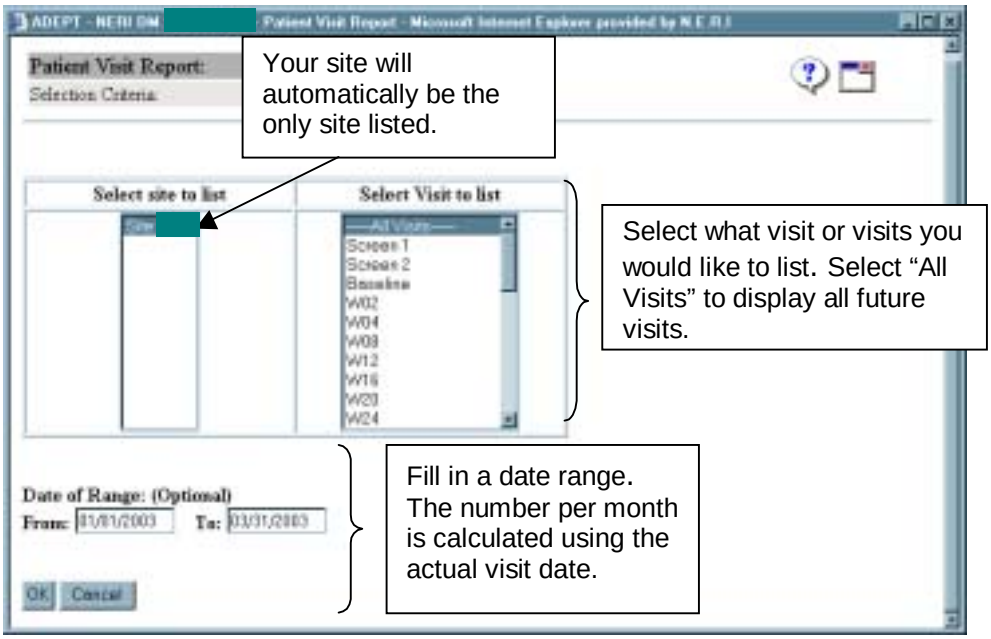
Displays the number of recruited patients for each month from the beginning of the study or within a specific time range.

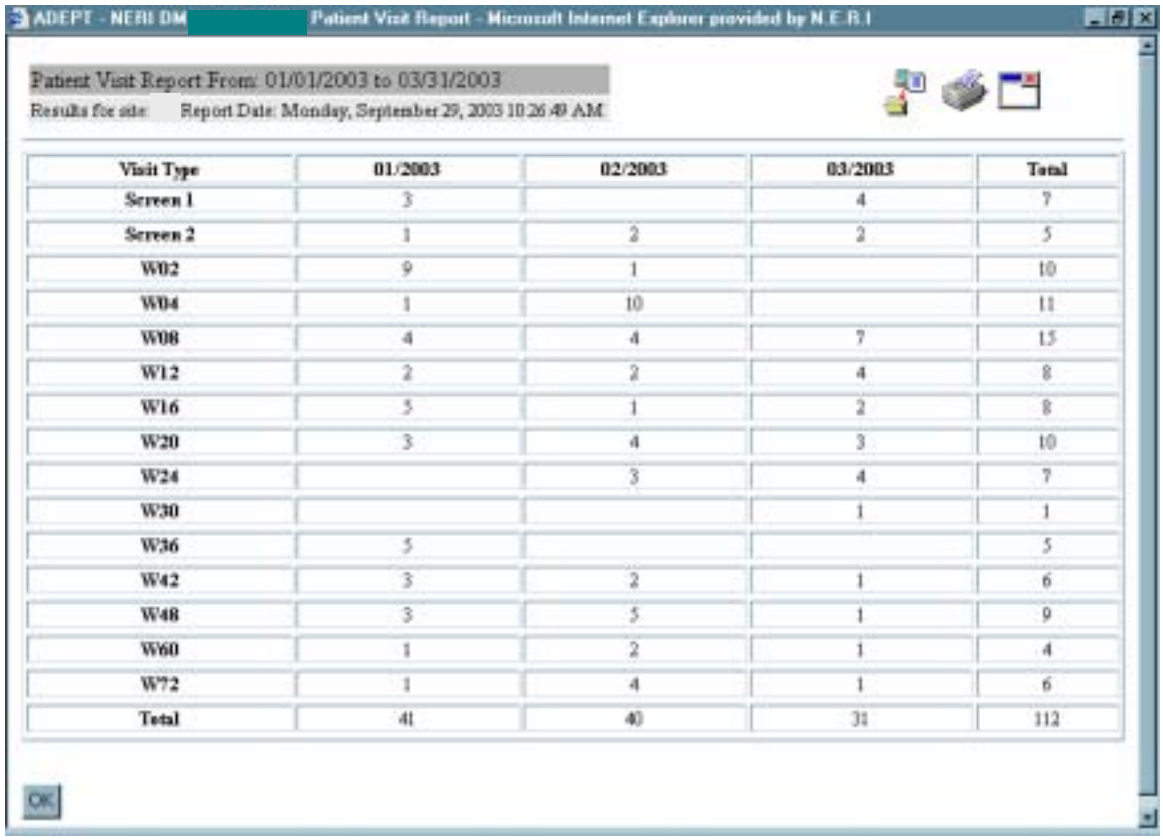
- **Recruitment Report by Race and Gender:**

Lists the recruitment broken down by race and gender from the beginning of the study or within a specific time range.

- **Patient Visits Report:**

This report lists all visits in each month based upon your data range. The number of visits is calculated using the actual visit date. This report gives you information about the **past**. It is used for **retrospective reports.** A sample report is given below.





Patient Visit Report From: 01/01/2003 to 03/31/2003

Results for site: Report Date: Monday, September 29, 2003 10:26:49 AM

Visit Type	01/2003	02/2003	03/2003	Total
Screen 1	3		4	7
Screen 2	1	2	2	5
W02	9	1		10
W04	1	10		11
W08	4	4	7	15
W12	2	2	4	8
W16	5	1	2	8
W20	3	4	3	10
W24		3	4	7
W30			1	1
W36	5			5
W42	3	2	1	6
W48	3	5	1	9
W60	1	2	1	4
W72	1	4	1	6
Total	41	40	31	112

OK

- **Monthly Randomization:**

Lists cumulative randomization in each month per site. You select a time range if desired. You may also check the “Detail patient type(Lead-In, Express, Relapser/BT)” box if you would like the report broken down by patient type.

- **NIH Race/Gender Report:**

Lists cumulative numbers of the patients at the different trail phases broken down by gender and by ethnic and racial categories.

D. Data Management Reports

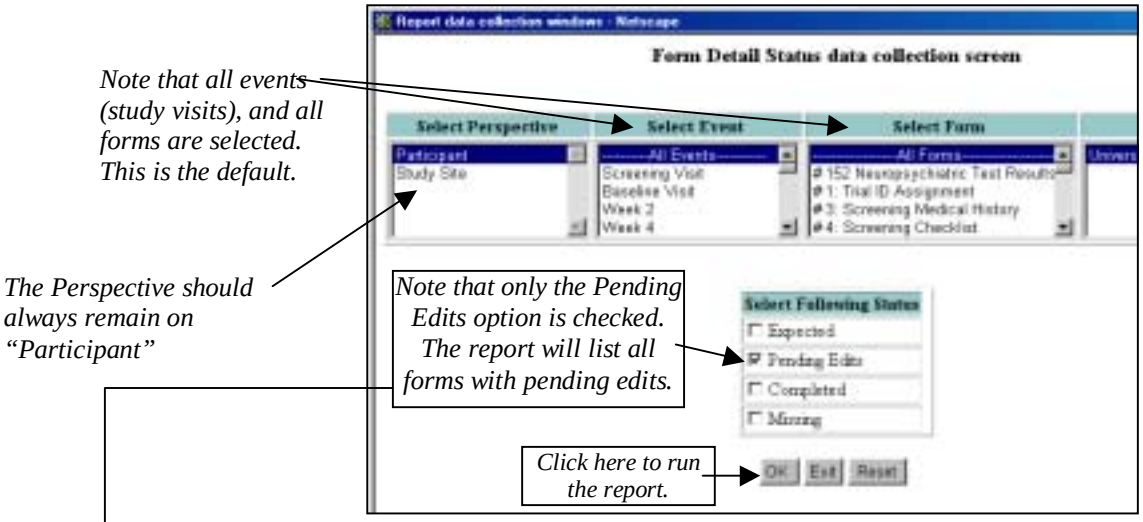
A number of reports are available to help in routine data management tasks. Site data management personnel should routinely run these reports in order to monitor the status of data forms at the site. The data management reports that are available are:

- **Detail Form Status Report:**

The Detail Form Status Report is very useful in tracking the status of forms at your site. It provides information on forms that have pending edits, forms that are expected, but not yet entered, forms that are complete and missing forms. Data management personnel should run the Detailed Form Status Report on a regular schedule to ensure timely and accurate data entry.

The default options display the status of all forms for all study visits. It is also possible to select a subset, by specifying particular forms, particular study visits or only some form statuses. To choose more than one item from the "Select Event" or "Select Form" list, hold down the <Ctrl> key while clicking on the items that you want to choose.

The screen that allows you to choose options for the Detailed Form Status report is displayed below. Clicking "OK" with these options will run the report for all forms at all visits and only forms with pending edits.



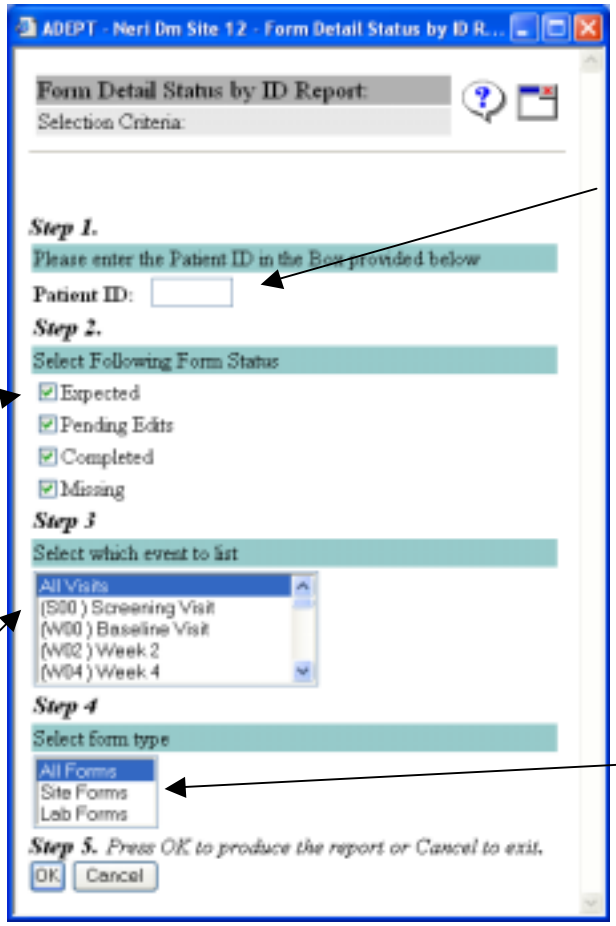
An example of the resulting Detailed Form Status Report is shown below.

Hepatitis C Antiviral Long-term Treatment against Cirrhosis
Detail Form Status Report for status: For site: University of Southern California
Form Status: Pending Edits
Date: 8-May-2002

ID	Initials	Visit	Form	Status	Completed Date	Completed By	Additional Desc.
17-002-7	ABC	M48	#51: Central Review of Pathology	Pending Edits	02/25/2001	EEE	
17-004-1	ABC	W00	#152: Neuropsychiatric Test Results - Cognitive Effects AS	Pending Edits	09/09/0909	CLB	
17-200-7	DDD	W30	#74 Week 20 Responders Aliquot Form	Pending Edits	07/04/2001	WWW	
17-200-7	DDD	W36	#74 Week 20 Responders Aliquot Form	Pending Edits	07/04/2001	SSS	
17-200-7	DDD	W42	#74 Week 20 Responders Aliquot Form	Pending Edits	07/04/2001	DDD	
17-200-7	DDD	W48	#74 Week 20 Responders Aliquot Form	Pending Edits	01/20/2001	OOO	

- **Detail Form Status by ID Report:**

This report allows a user to look up each form and form status listed for a specific patient.



Enter a Patient ID to see forms for one particular patient.

If you would like to search for forms that are expected only, uncheck the other boxes.

Select a specific event from the list. You can select multiple events by holding the <Ctrl> key while making your selections.

Sites should always select "Site Forms" so that they only see forms that are available for entry at their clinical site.

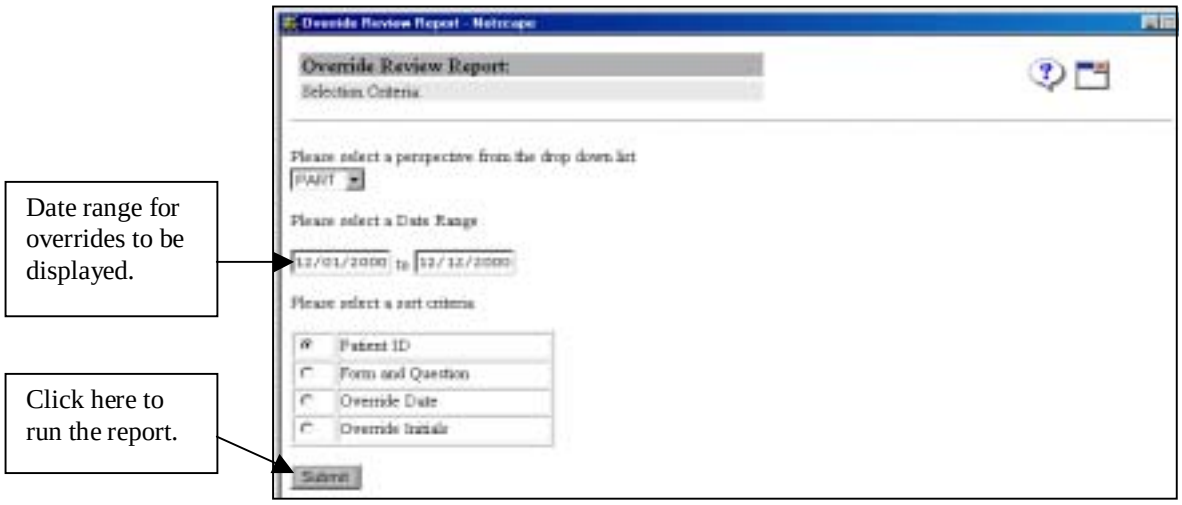
- **Missed Visit Report (List Missed Visits):**

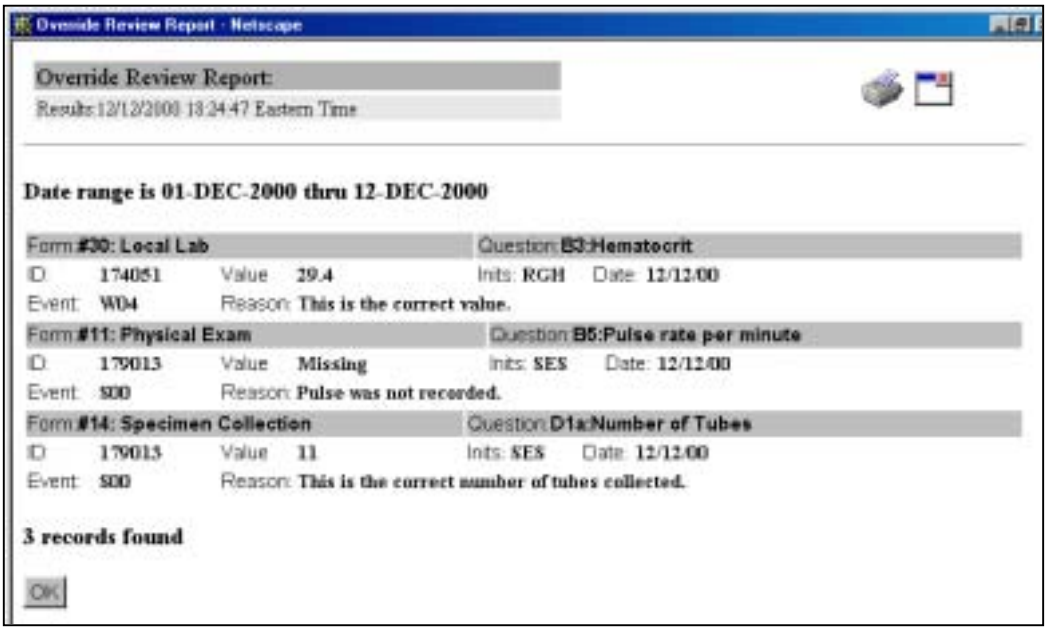
This report allows you to check if any visits have been missed (Form #24 entered). You can choose a date range to search through and you can choose to sort by patient ID, window end date or a combination of the two.

- **Override Review Report:**

After selecting a date range, this report prints out a listing of overrides done on forms during that period. This report can be sorted either by patient ID, form and question, the override date or the initials of the person who performed the override.

For example, when the following report is run, it will display information about overrides that were set between 12/01/2000 and 12/12/2000.





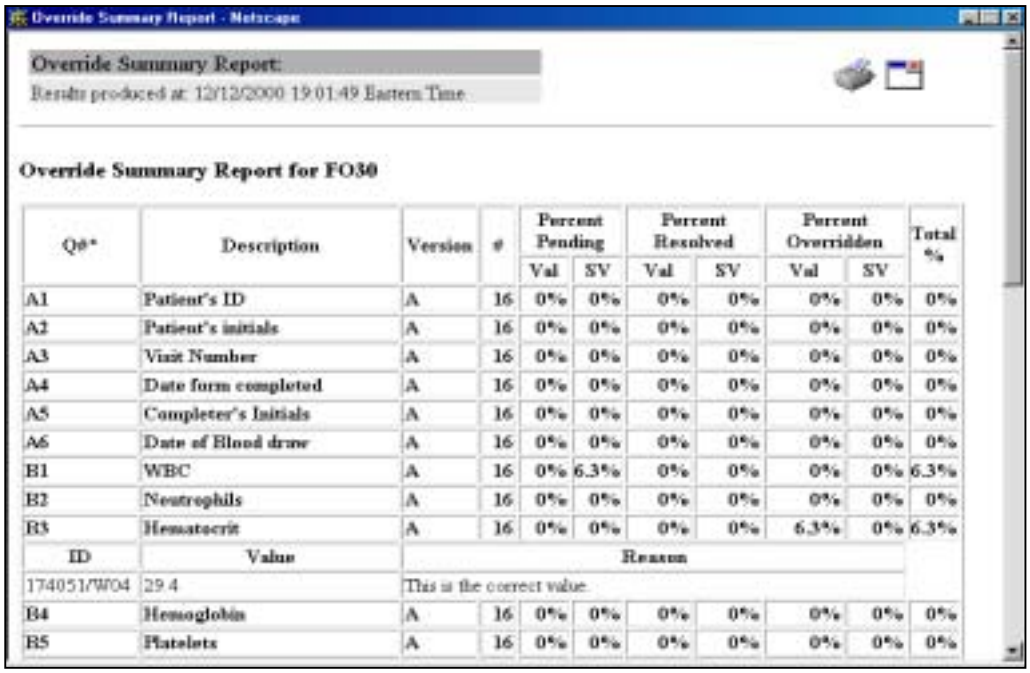
- **Outstanding Forms List:**

Lists all forms not yet data entered if the last day of the visit window has passed by two weeks or more.

- **Override Summary Report:**

Lists all the overrides done on a particular form. To run the report, select a form from drop-down menu. The report displays each question on that form and the percentage of values that has been overridden, resolved and/or has pending edits for each question.

A sample report for Form # 30 is shown below. Note for question B1, 6.3% of the answers are pending. For question B3, 6.3% of the answers have overrides. If a particular question has values that were overridden, each instance is listed, with the patient ID, event, value overridden, and override reason.



Override Summary Report - Netscape

Override Summary Report:

Results produced at: 12/12/2000 19:01:49 Eastern Time

Override Summary Report for FO30

Q#*	Description	Version	#	Percent Pending		Percent Resolved		Percent Overridden		Total %
				Val	SV	Val	SV	Val	SV	
A1	Patient's ID	A	16	0%	0%	0%	0%	0%	0%	0%
A2	Patient's initials	A	16	0%	0%	0%	0%	0%	0%	0%
A3	Visit Number	A	16	0%	0%	0%	0%	0%	0%	0%
A4	Date form completed	A	16	0%	0%	0%	0%	0%	0%	0%
A5	Completer's Initials	A	16	0%	0%	0%	0%	0%	0%	0%
A6	Date of Blood draw	A	16	0%	0%	0%	0%	0%	0%	0%
B1	WBC	A	16	0%	6.3%	0%	0%	0%	0%	6.3%
B2	Neutrophils	A	16	0%	0%	0%	0%	0%	0%	0%
B3	Hematocrit	A	16	0%	0%	0%	0%	6.3%	0%	6.3%
ID	Value	Reason								
174051/W04	29.4	This is the correct value.								
B4	Hemoglobin	A	16	0%	0%	0%	0%	0%	0%	0%
B5	Platelets	A	16	0%	0%	0%	0%	0%	0%	0%

Abbreviations used in the output:

"Val" refers to values out of range.

"SV" refers to the fact that special values (e.g. –9) were used.

- **Monthly Tasks Report**: There are two reports listed under this submenu:
  - Ineligible Patient Report – The report lists all ineligible participants at your clinical center. Participants only stay on this list for five months after ineligibility is determined by Form #3
  - Prescreening Patient Report – The report lists all prescreening participants at your clinical center.

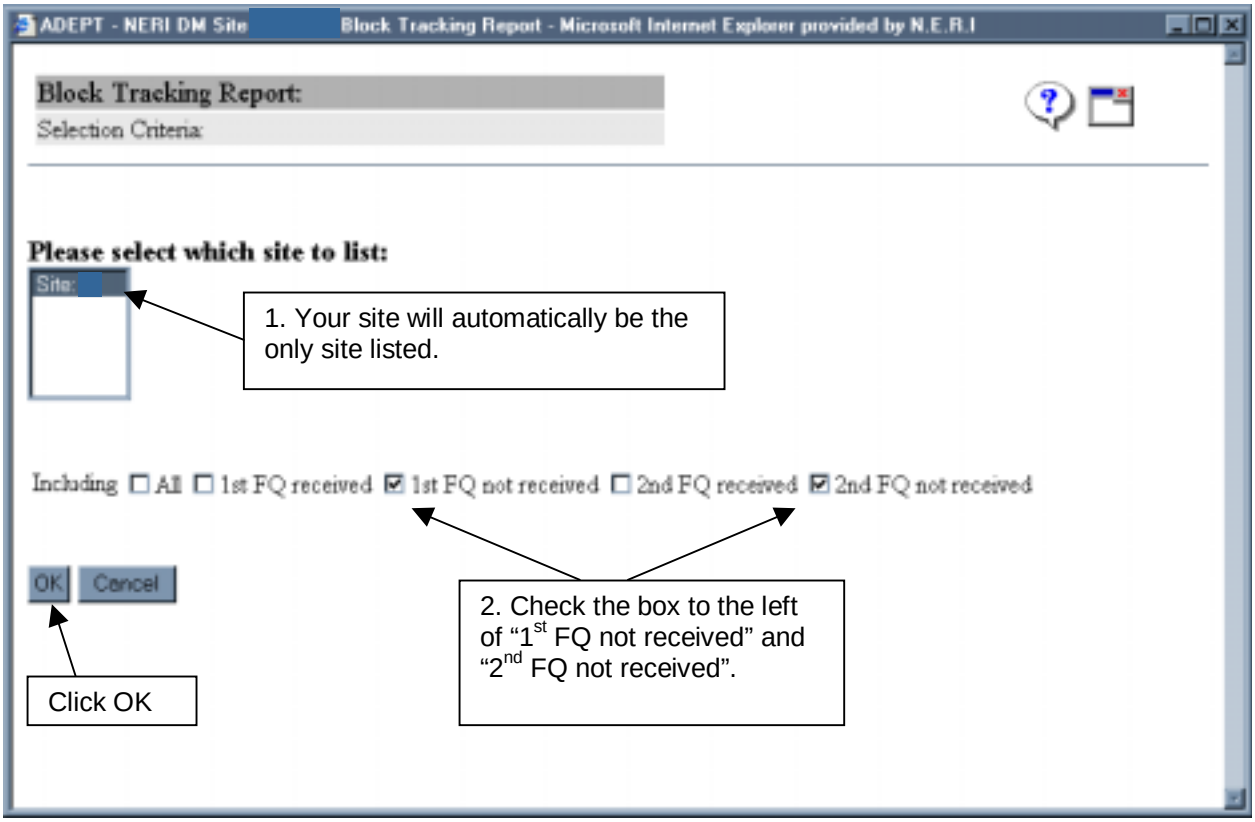
- **Outstanding Form 26 List:** Displays a list of all Forms #26 (Pegasys Accountability Log) that are outstanding.

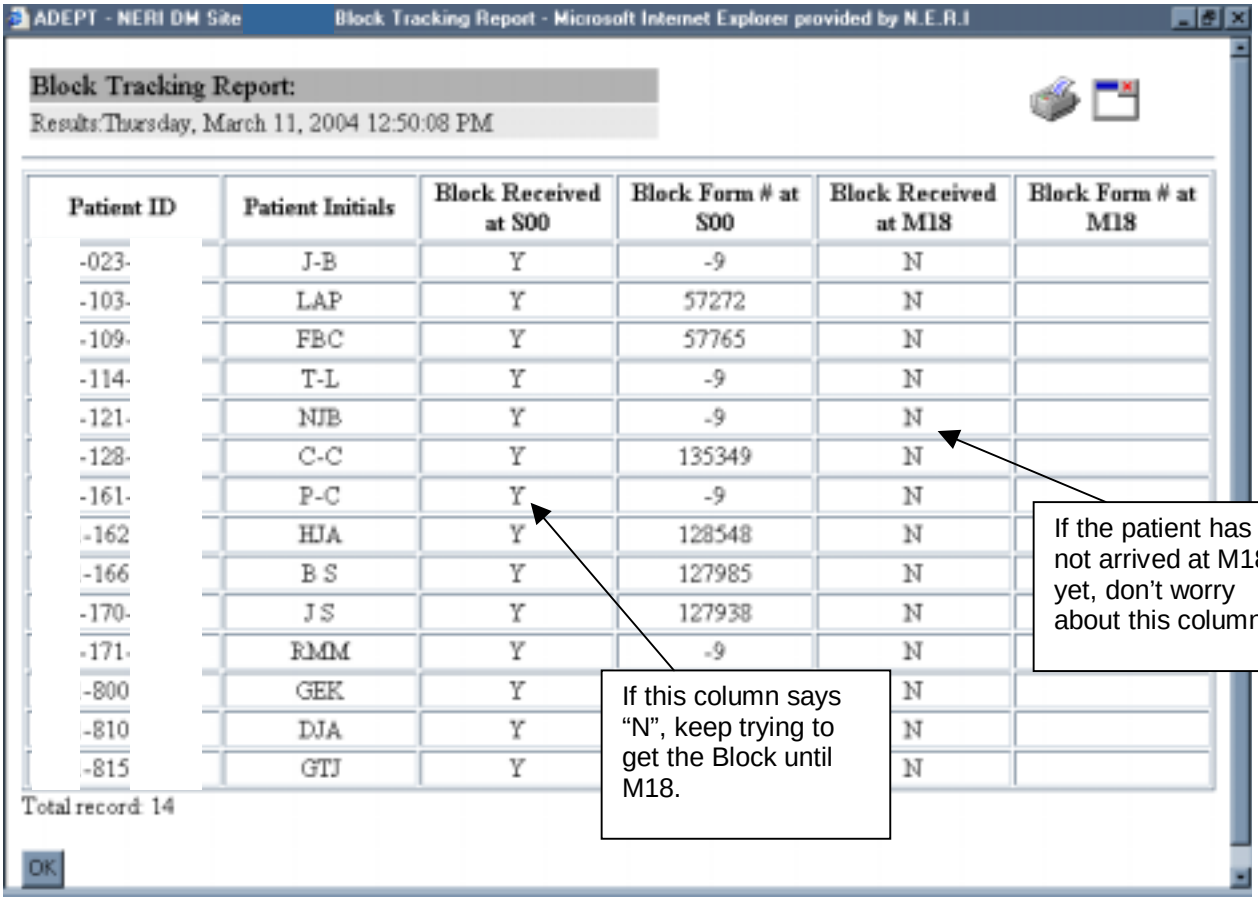
E. Tracking Reports

These reports provide a list of patient-specific items to be forwarded to NERI, tracking what materials are outstanding/expected in the DMS. These tracking reports are:

- **Expected Biopsy Listing:** List of biopsies expected at the DCC
- **Expected Endoscopy List:** List of endoscopy photos expected at the DCC
- **Block Tracking:** Reports the Block Food Questionnaires received and those still expected. When you open the report, check the box to the left of "1st FQ not received" and "2nd FQ not received" and click OK. Check to see if this patient is on the list. If so, add a Block to the packet of forms. If a patient is randomized, collect S00 Block up to M12. If M12 is passed, let the DCC know, and they will set it to missing. If the patient is a responder, collect the S00 Block up to W36. If a patient has not completed their M18 Block, continue to try to get it until the patient is no longer in the study. If

the patient has refused to complete the Block or they do not speak or read English well enough to complete the questionnaire, inform the DCC and they will set it to missing.



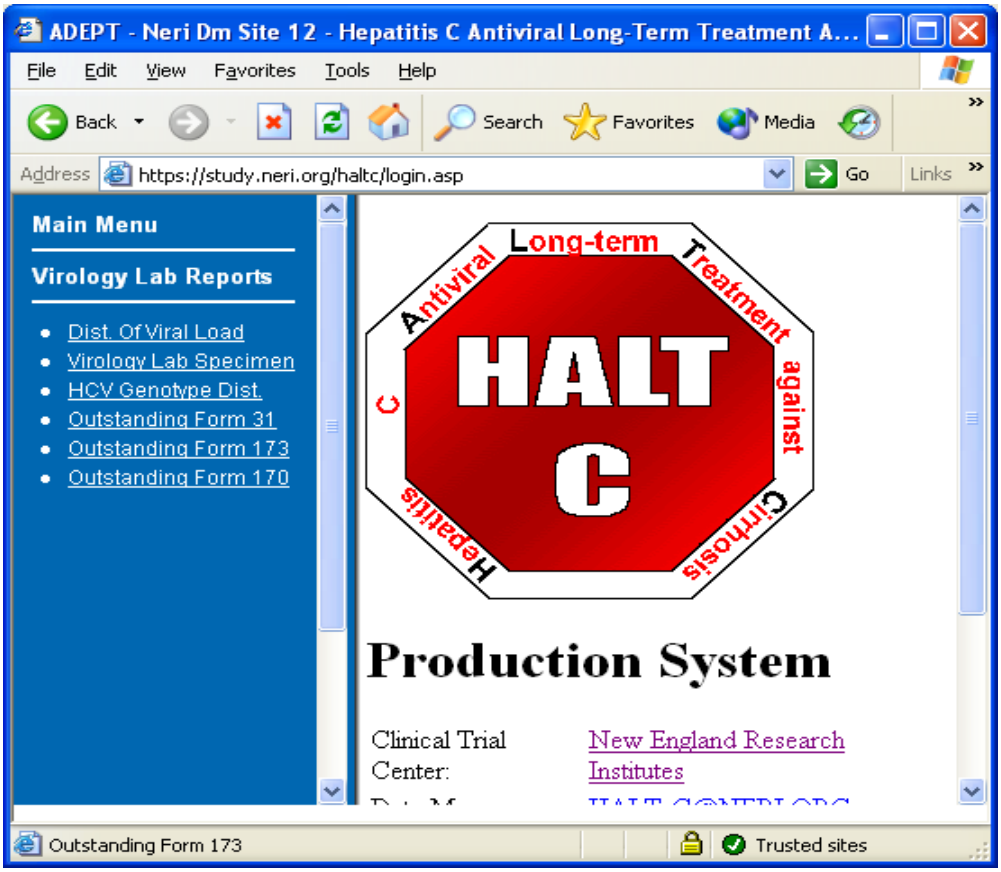


If it says “Y” in the “Block Received at S00” column or the “Block Received at M18” column, that means the Block has been received or set to missing by NERI. If it says “N”, that Block still has not been received.

- **Site Outstanding QC:** Lists forms selected for QC, but not yet double data entered at the DCC
- **Expected CIDI Report:** Lists CIDIs files expected at the DCC
- **Site Pending Edits:** Lists all pending edits at the clinical center for only those forms data entered at that clinical center.
- **Site Outstanding Forms:** Lists forms not data entered where two weeks or more have passed since the visit window closed. Only those forms data entered at that clinical center are listed.

- **Site Freezer Inventory:** This report lists all specimens still at your clinical center based on your search parameters. You can sort the data by Patient ID, visit, sample ID, or collected date. The report displays the sequence # and the number of specimens for a patient at a certain visit.

III. Virology Lab Reports



- **Distribution of Viral Load:**

This report shows specimens received and results data entered by the Virology Lab for all sites. You can sort the data by patient type and you can set up a data range.

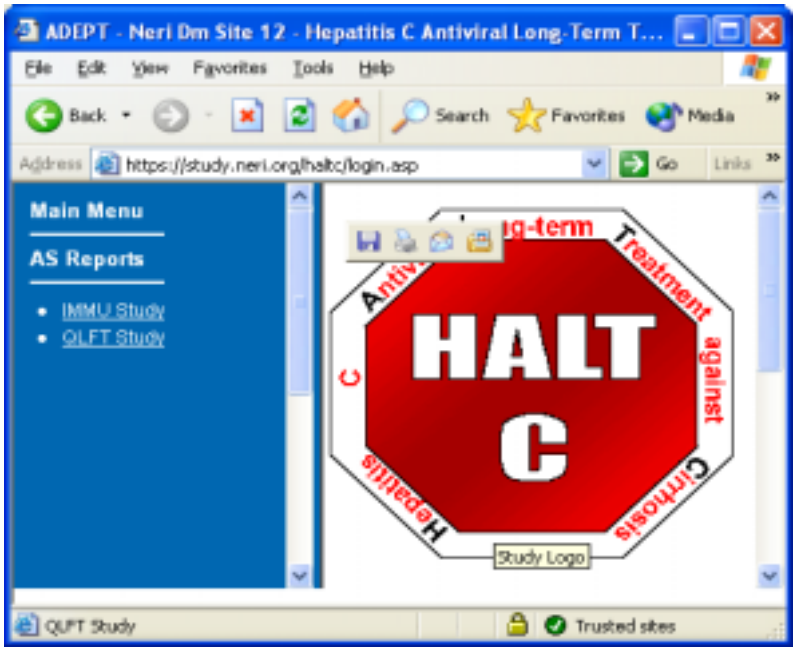
- **Virology Lab Specimen:**

This report shows the total number of specimens received and reported (entered) by the Virology lab for all sites by visit number. You can modify your search by stetting up a specific date range.

- **HCV Genotype Distribution:**

This report displays the distribution of HCV Genotype test results in the DMS for your clinical center. The report displays the results by total count and by percentage.

IV. Ancillary Studies Reports



A. Immunology/Virology Ancillary Study

- **Baseline Immunology /Virology Specimen Collection:**

This report displays the Immunology/Virology specimen collection at your clinical center. The report includes the following variables: Patient ID, Trial Status, Screen Date, CTL Blood (S00), CTL Liver (S00), Replication (S00), Baseline Date, NA (W00), Quasi (W00), LP (W00), and F176.

- **CTL Shipping Report:**

This report shows CTL shipping data. It lists the Patient ID, Patient initials, Visit, CTL Specimen Type, Date Shipped, Date Received, and the condition of the specimen. You can also specify a date range for this report.

- **CTL Unavailable Liver/Ineligibility Report:**

This report shows which patients are participating in CTL AS but are either ineligible for HALT-C trial or have not had sufficient liver collected at the screening biopsy for CTL study. The report displays Patient ID, Old ID, Patient Initials, Eligibility for Trial, Date of CTL Blood Draw, Number of Tubes Collected, CTL Liver Collected, Date Of Biopsy, and CTL Liver From Form # 501.

- **LP Shipping Report:**

This report shows LP shipping data for your clinical center. It lists the Patient ID, Patient Initials, Visit, Collected Date, Date Shipped, Date Received, and Condition of the specimen. You can also specify a date range for this report.

- **Month 24 Immunology/Virology Biopsy Report:**

This report lists M24 visit Immunology/Virology liver biopsy requirement for each patient in the next 3 months at your clinical center. You can sort the data by Participant ID or visit window. The report displays Patient ID, Patient initials, Month 24 Visit Window, and the reasons why liver was or was not required to be collected.

B. QLFT Ancillary Study

- **SPECT Scan**

  - **No Received Date Report** – The time between the visit date and today's date is more than one month and Dr. Wittry still has not received SPECT. If Form 192 has been entered, the item will not show up on this report. Only Sites 14 and 19 are listed in this report. Only sites 14 and 19 and NERI can see this report.

  - **Form 192 Expected Report** – Lists Form 192 as Expected only if Dr. Wittry has sent the SPECT scan to UCI for processing.

V. Site Map

The Site Map is a report especially designed to provide a listing of all reports available to ADEPT users. The report is site specific and will show only the reports that a particular user has access to.
To Site Map is located under the main menu and it will automatically bring you to the report you are looking for.
You can use it to search for a report, even if you are not sure what the exact report name is. As long as you enter a part of the name, you will be provided with a list of reports whose title includes the word(s) you have entered in your search.