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User Guide of the ezTrial (beta) Clinical Trial Information Management System

Yi-Ru Cian , Chung-Tsuo Lin , Hong-Yi Chen, Chia-Hui Chang, Yi-Fang Lee, and Chun-Nan Hsu

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ezTrial

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2010/6/8

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1. ezTrial

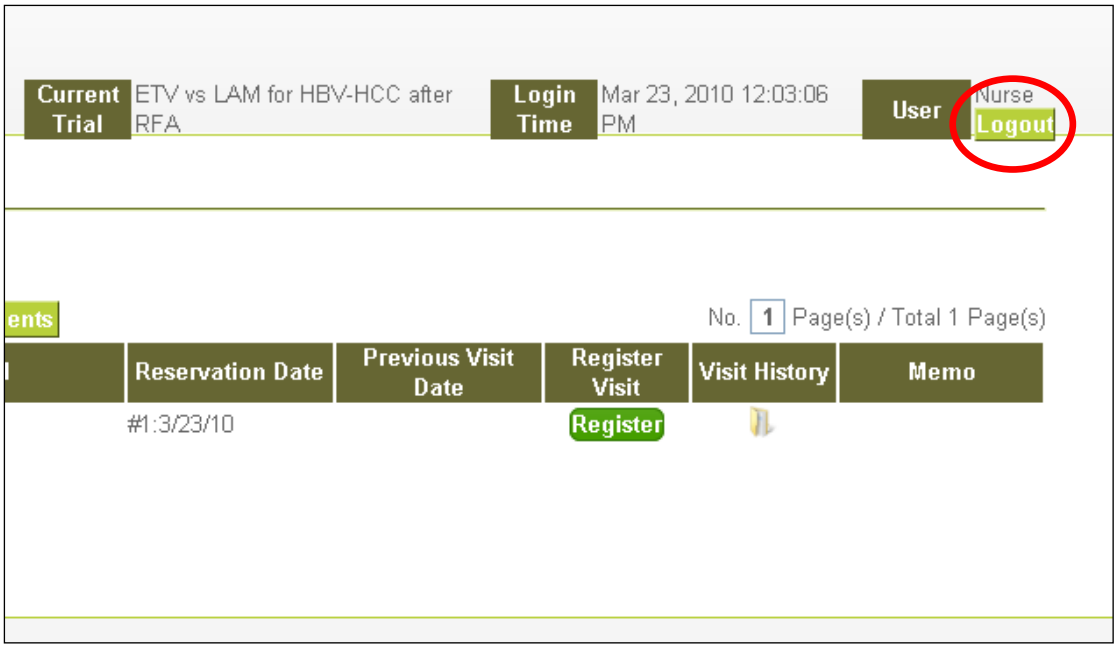
1.1 System Login & Logout

1.1.1 Login

- Open your web browser and input the ezTrial URL: https://cims.biomed.org.tw/ezTrial
- On the ezTrial login page (shown below), enter your account and password
- Click the **[Log in]** button

1.1.2 Logout

- Click the **[LOGOUT]** button in the top right-hand corner of the screen.
- The system will then return to the login page.

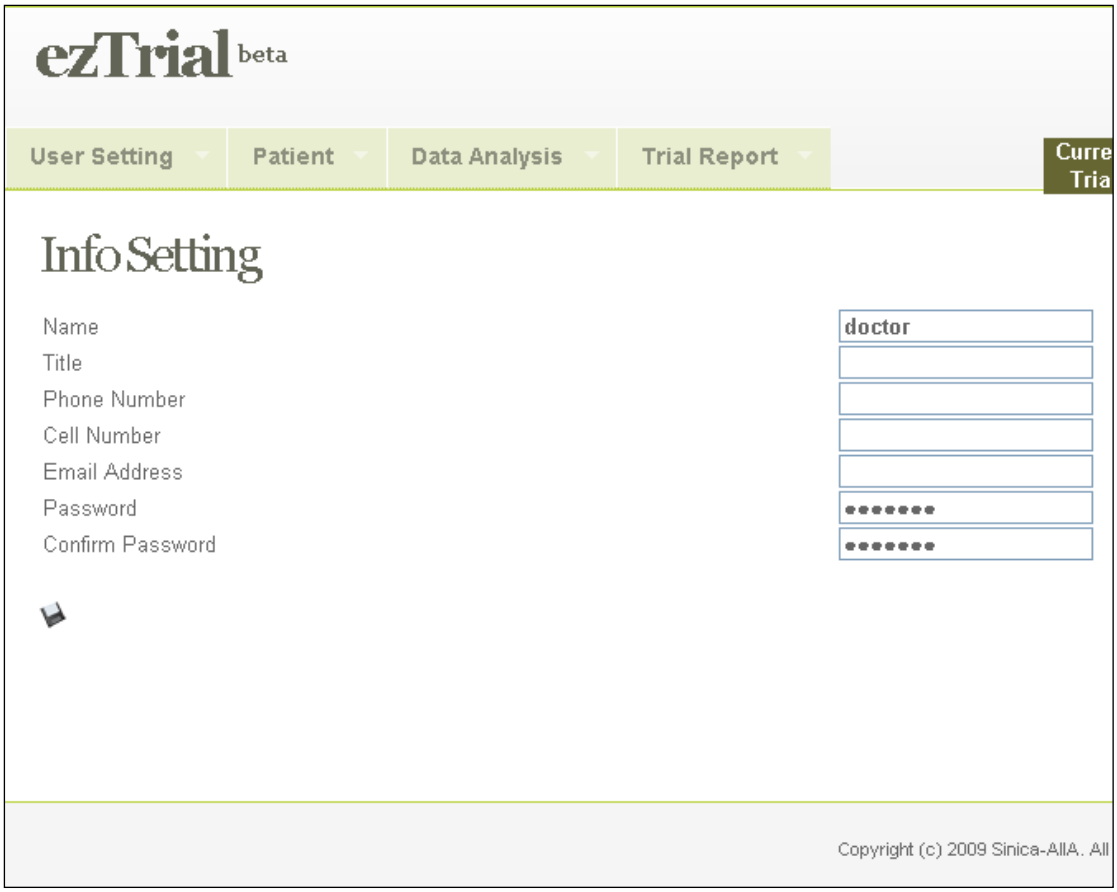


2. ezTrial Functions

2.1 User Setting

2.1.1 Info Setting

This function allows you to edit your account information. To save edited data, simply click the [Save] button.



2.1.2 Switch Trial

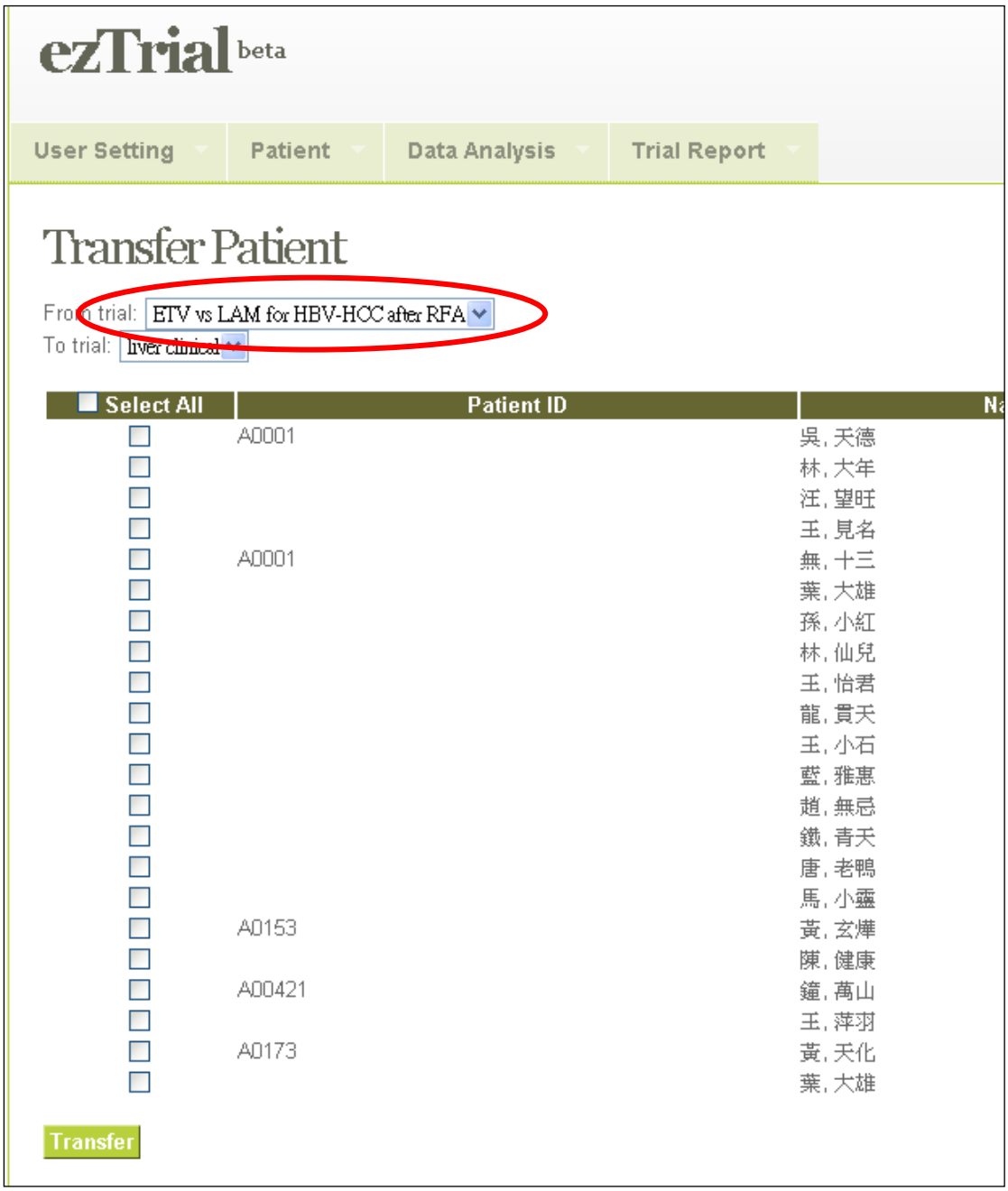
After logging into the system, if you do not have a current trial, the system will redirect you to the switch trial page. You can then select a current trial on this page, and click the **[Save]** button to store the setting. The next time you log in, the system will display the Today's Visit page of the trial setting stored previously.

If you wish to switch from the current trial setting to another one, just click on the menu **[Switch Trial]** under **[User Setting]**. Then, repeat the switch trial setting steps.

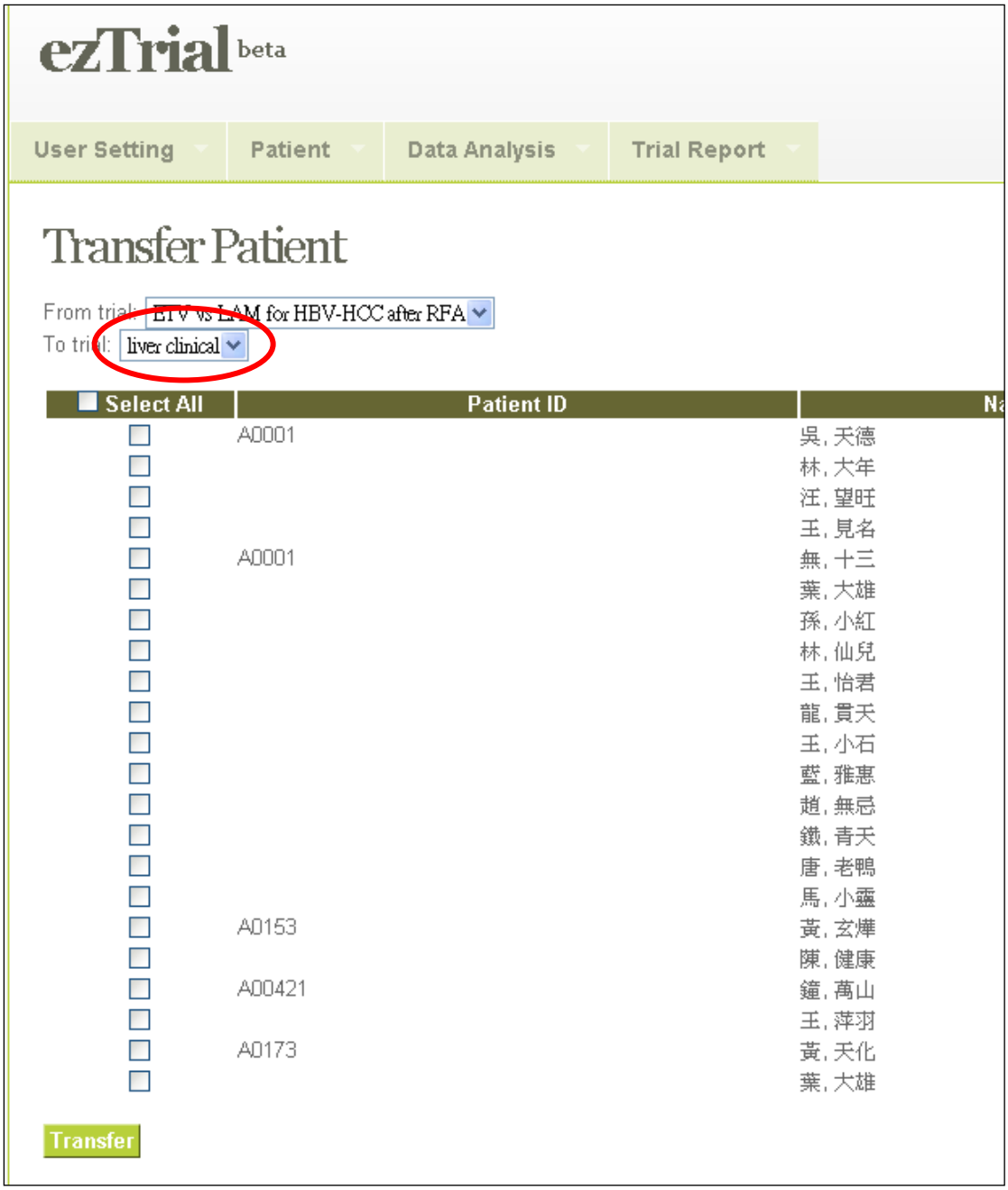
2.1.3 Transfer Patient

This function can only be used by doctors to copy patient information from one trial to another trial.

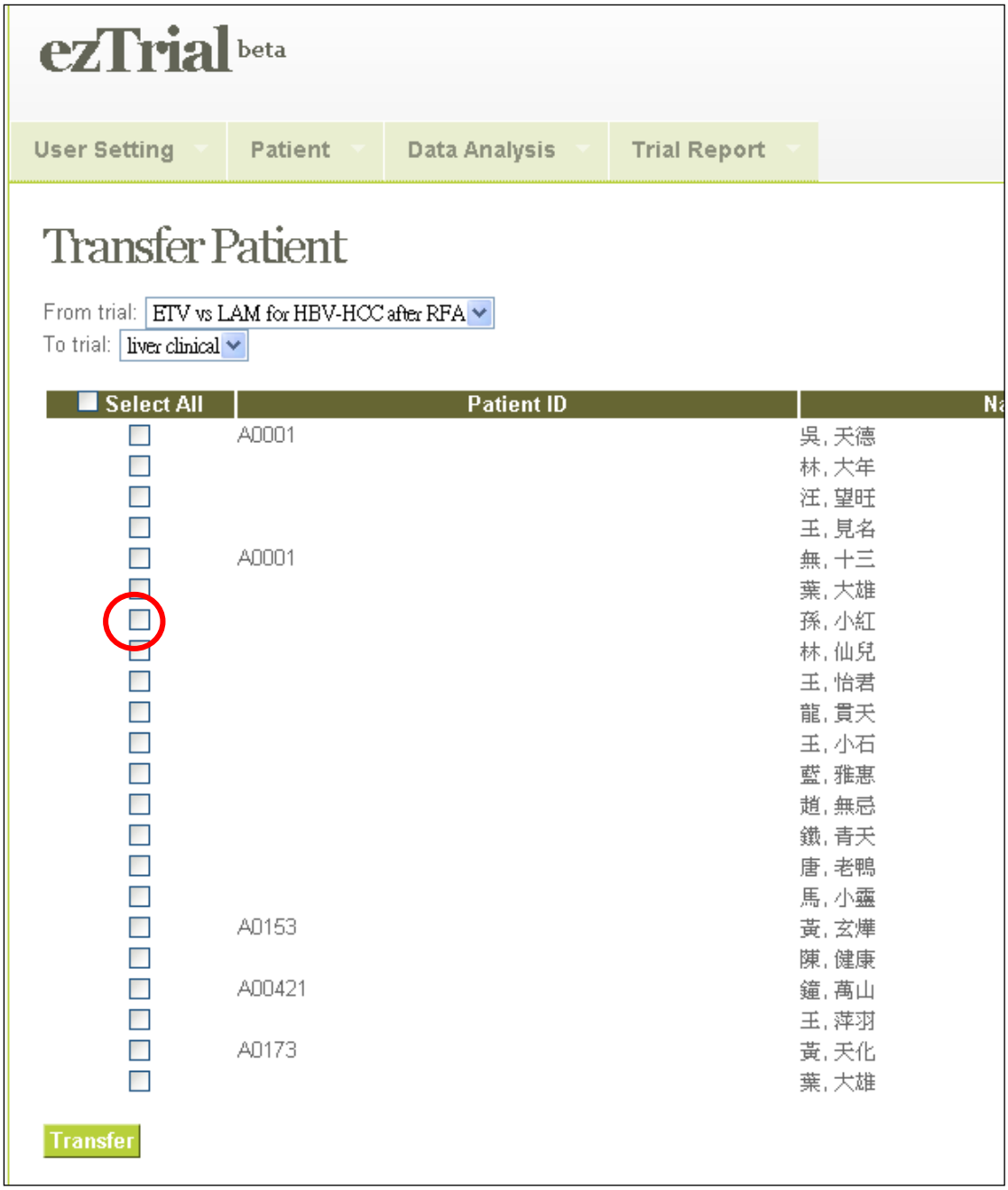
First, select the trial of the patients whose information you want to share with another trial.



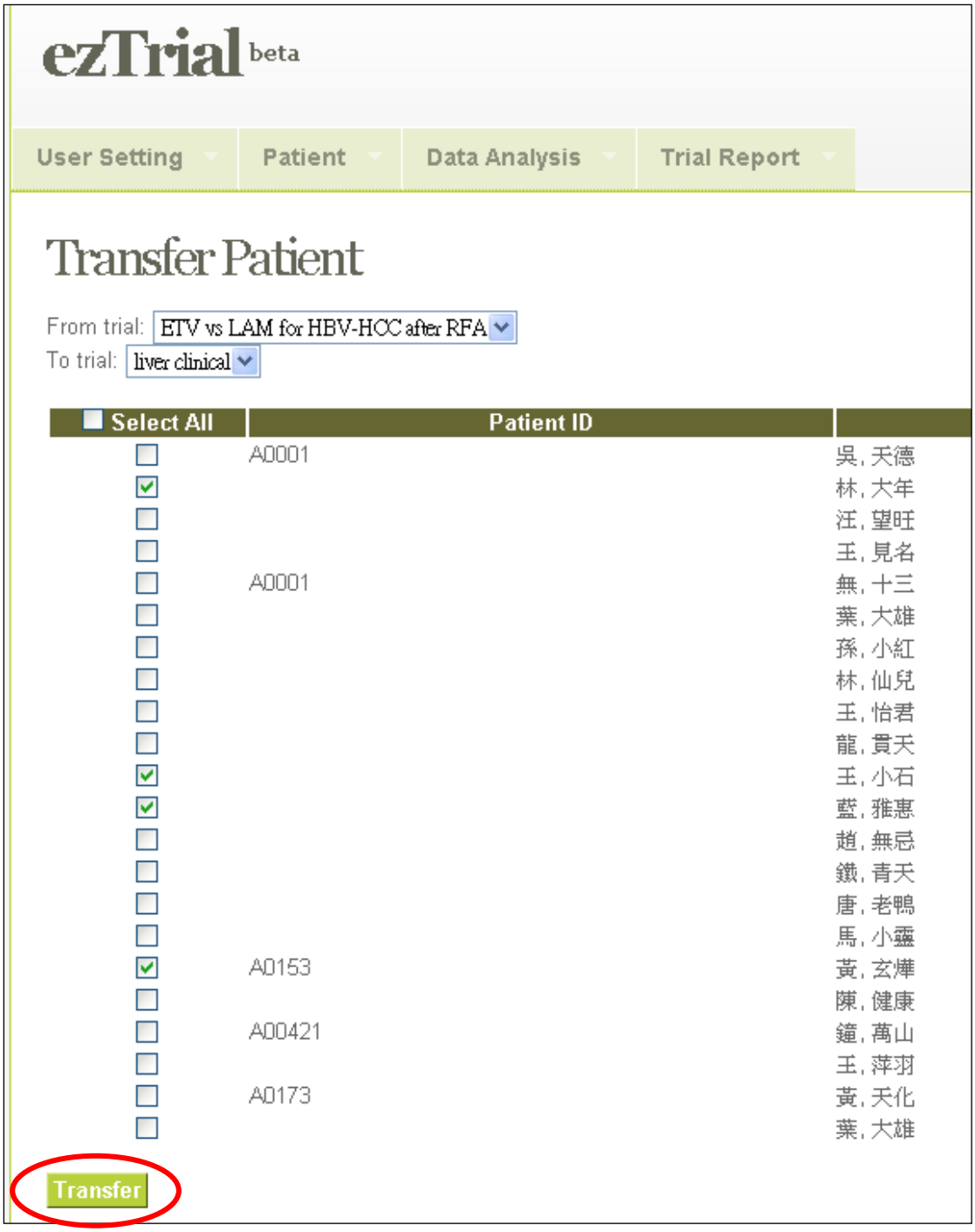
Second, select the trial that you want to share the information with.



Third, select the patients whose information you want to share.



Finally, click the **[Transfer]** button. The system will then copy the information to the trial you select.

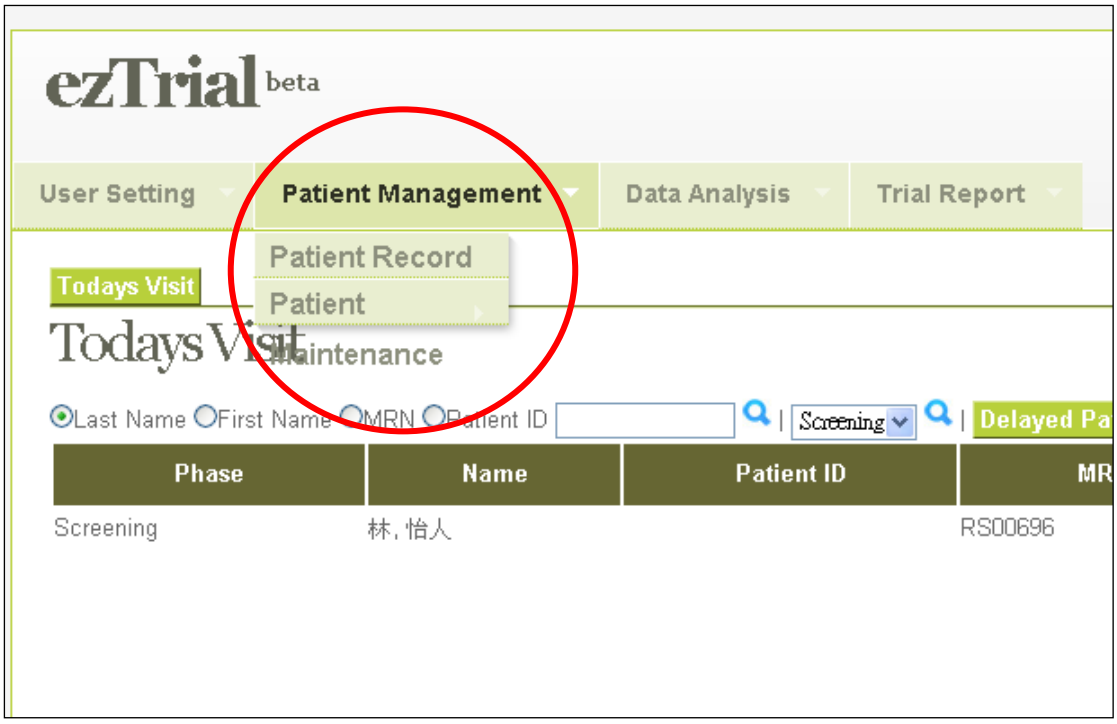


After the information has been transferred, the patient's name will be removed from the list.

2.2 Patient Management

Hold the cursor over **[Patient Management]** to open the Patient Management menu.

Use the menu to add a new patient to the trial and complete the appropriate record in the system with the schedule of the trial.



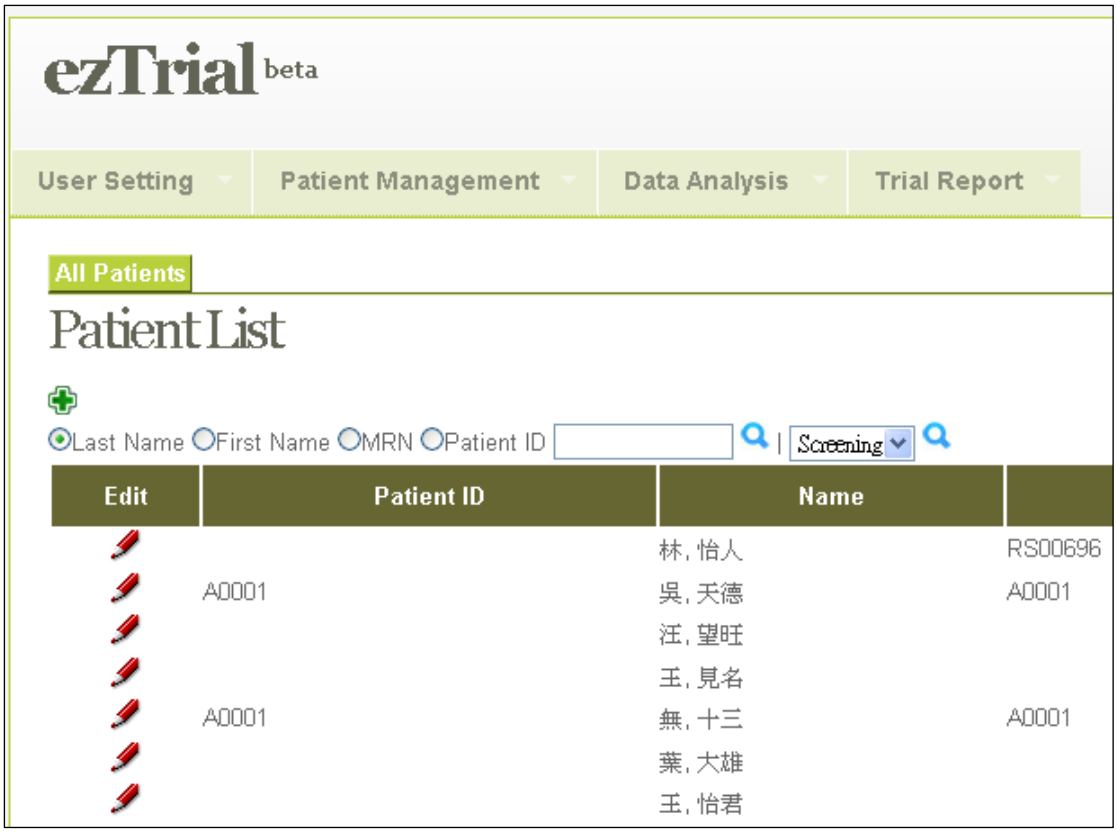
2.2.1 Patient Maintenance

Patient Maintenance is divided into two parts –
Patient Info and **Withdraw Patient**.

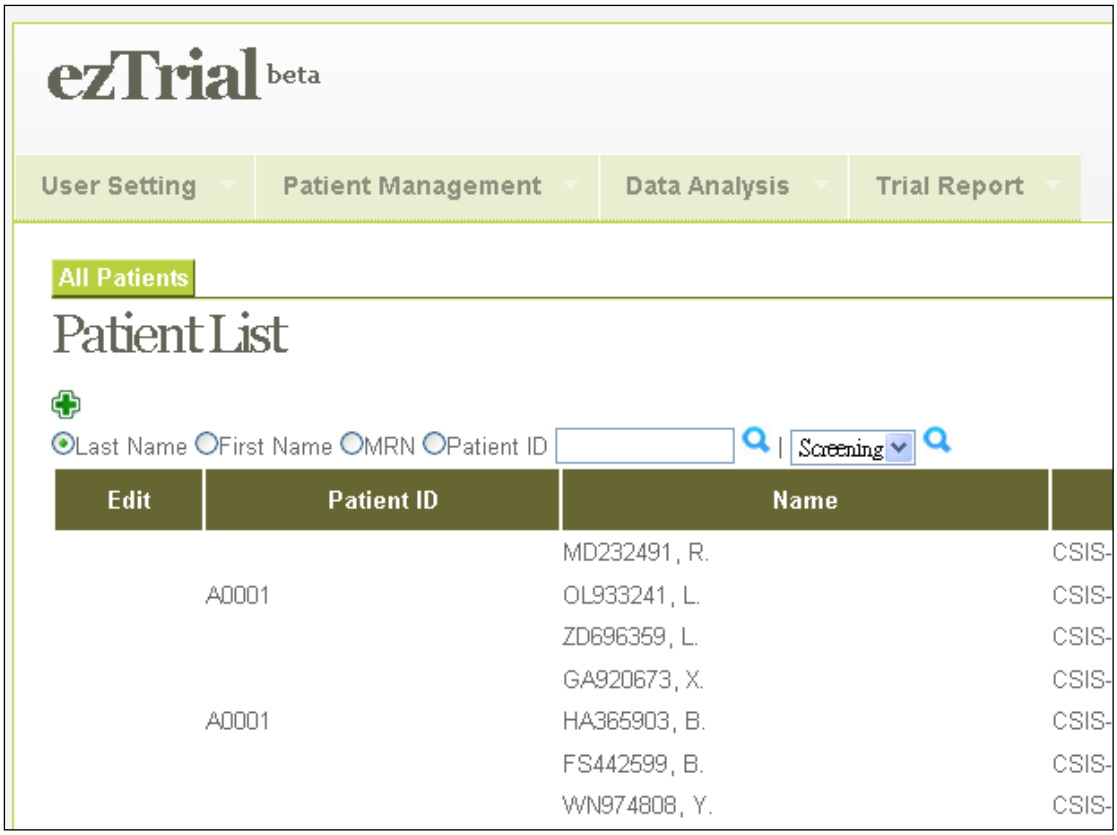
In **Patient info**, you can add a new patient to the trial or edit the data of patients already in the trial if you have permission. You can also assign a patient to the next phase or withdraw a patient from the trial.

In **Withdraw Patient**, you can check the data of patients who have been withdrawn from the trial.

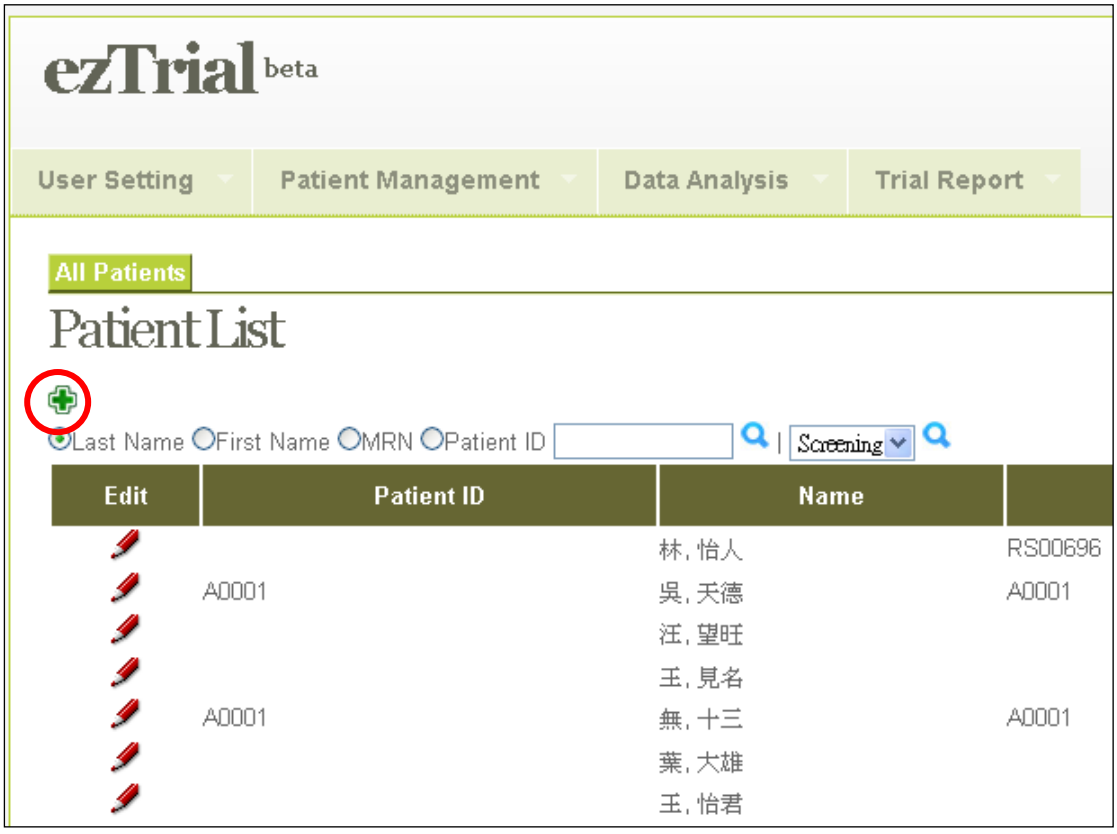
Patient Info:
When you click the **[Patient Info]** button, the system will display a list of all patients in your trial, but not patients who have been withdrawn.



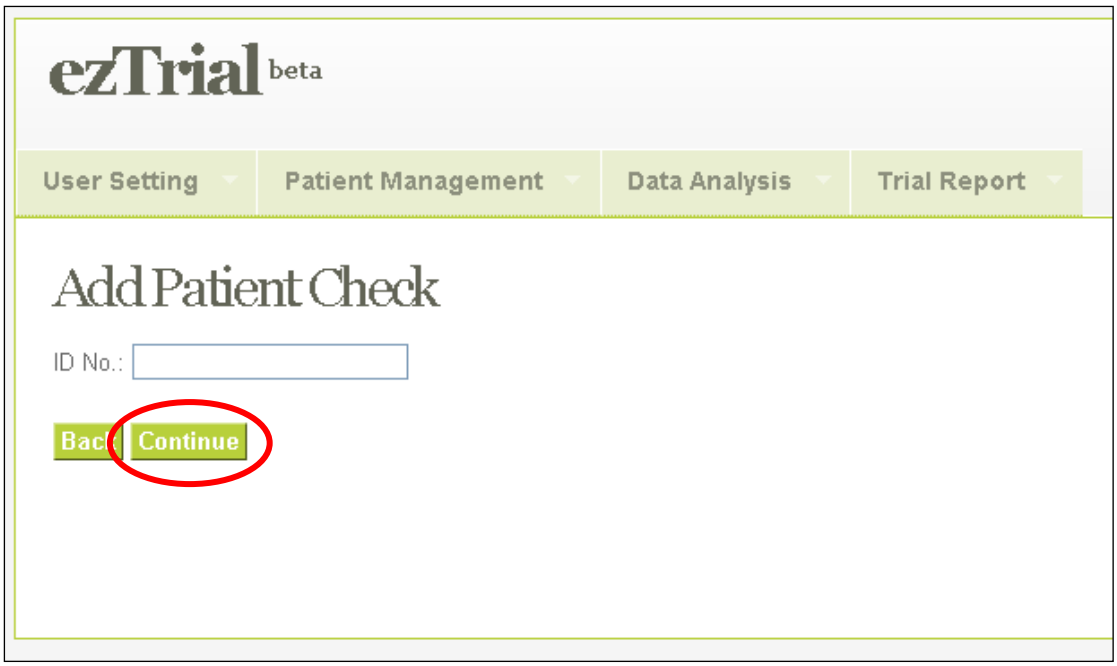
If you do not have permission to access PII (Personally Identifiable Information), the system will not allow you to obtain patient information.



Click the **[ADD]** button to add a new patient to the trial you have selected.



When you click **[Add Patient]**, you will be asked to enter the patient's I.D. number on the following page to avoid duplication.

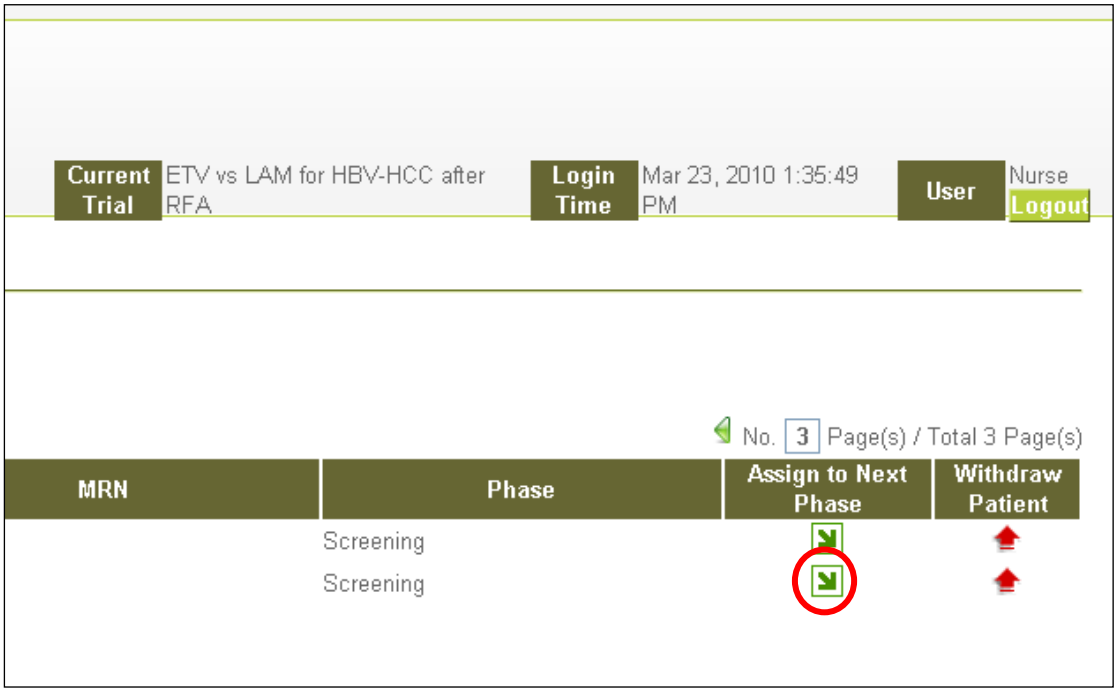


After entering the I.D. number, click **[Continue]**. If the I.D. number you have entered is already in the system, ezTrial will not allow you to create a new patient entry. The system will only allow you to edit the patient's data if you have permission.

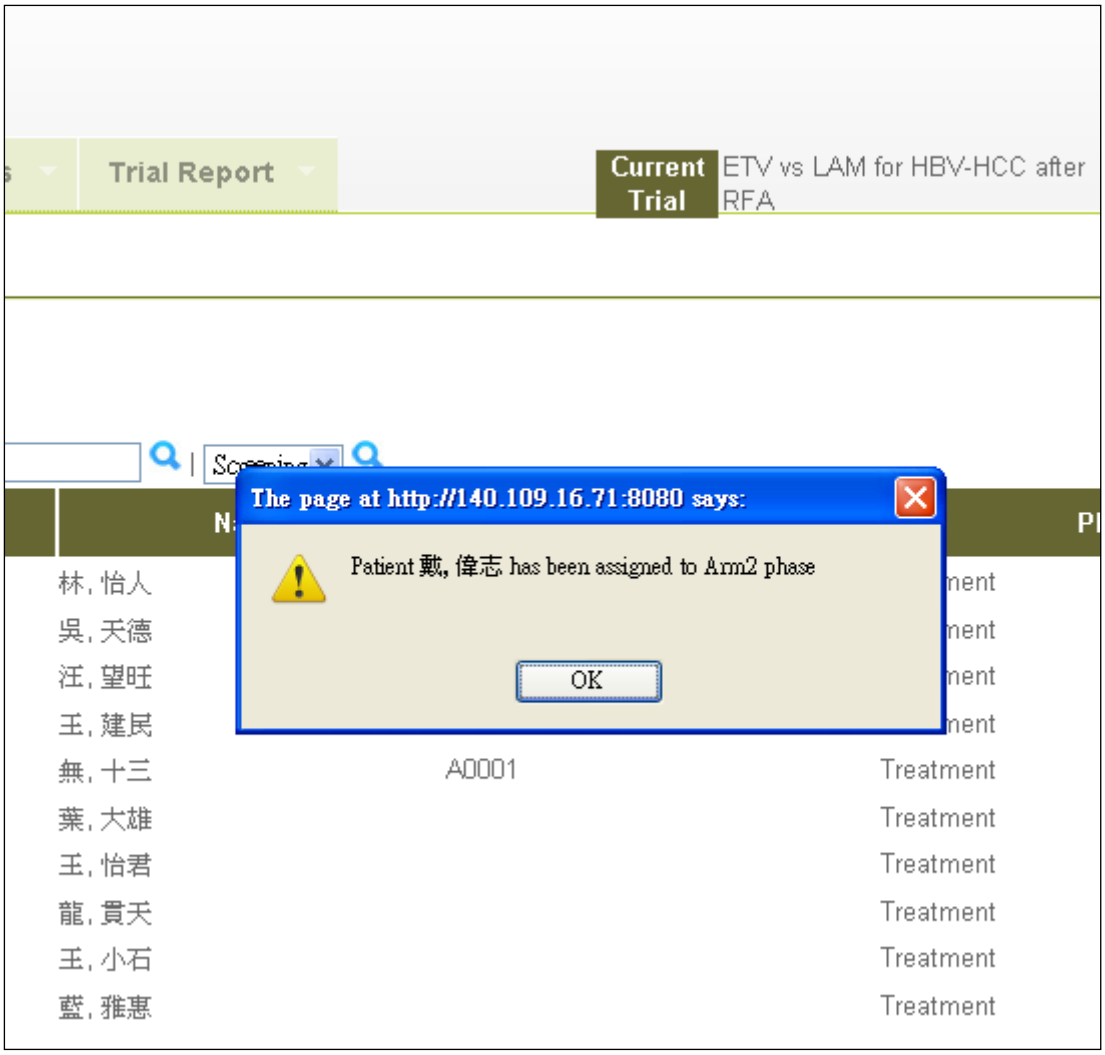
When you have finished entering the patient information, click **[Save].** The system will update the patient list for your trial, and assign the patient to the first phase of the trial.

If you have PII permission, you can also edit patient information by clicking the **[Edit]** button. When you finish editing and click the **[Save]** button, the system will display the information for you to confirm the entry.

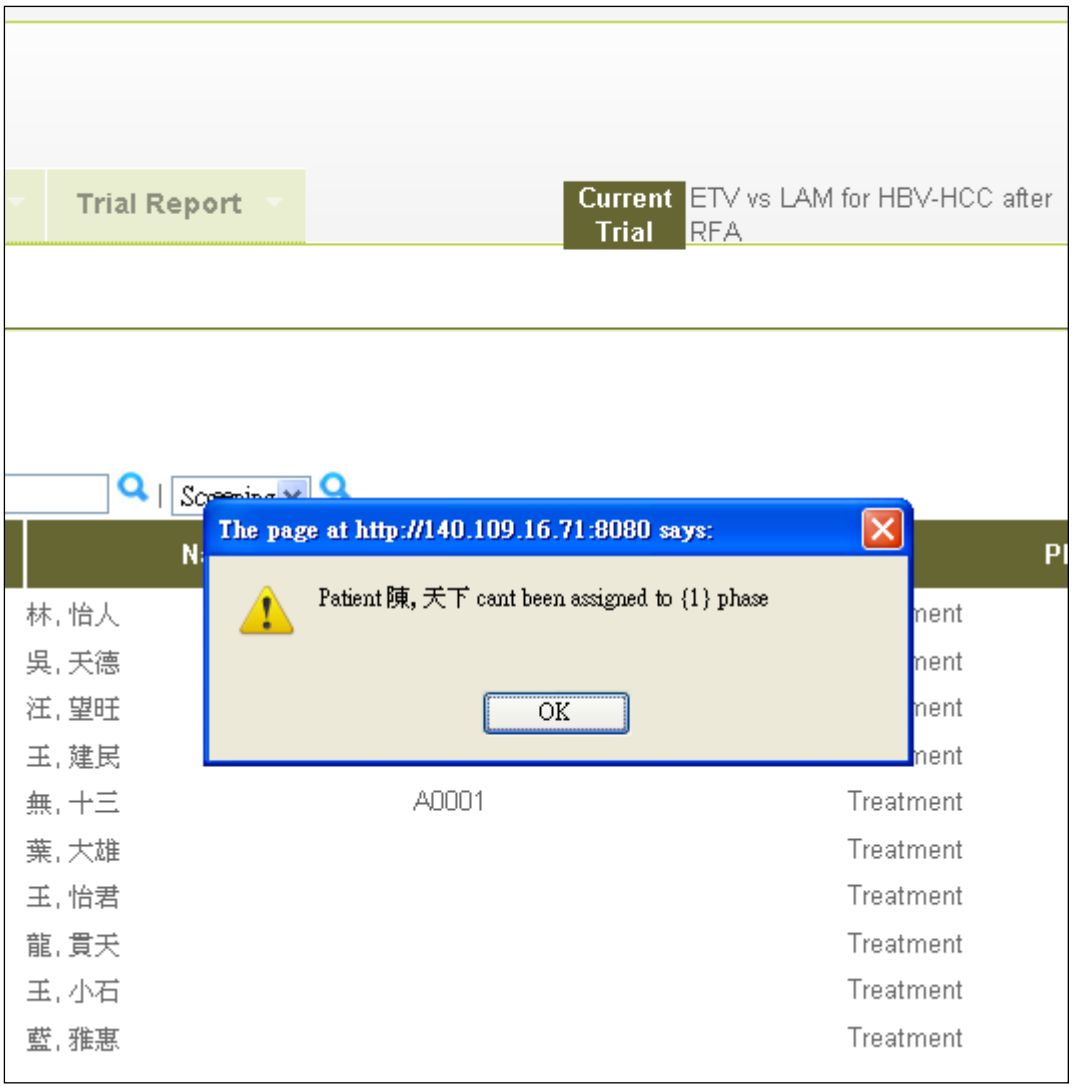
When you want to assign a patient to the next phase, you should click on the **[Assign to Next Phase]** button in the same row as the patient's name.



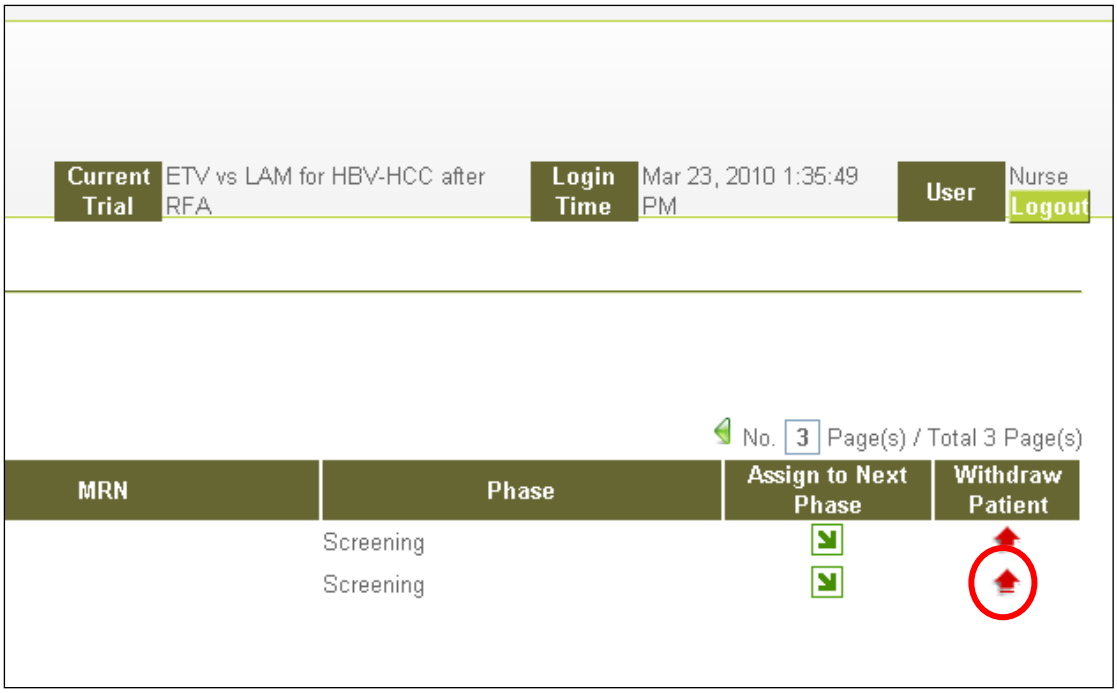
The patient will be assigned to the phase indicated by the system.



If any required fields are left blank, the system will display an error massage.



To withdraw a patient from the trial, click the **[Withdraw]** button.



You must select Withdrawn Status and complete the Withdrawn Comment section.

After clicking the **[Save]** button, the system will update the information.

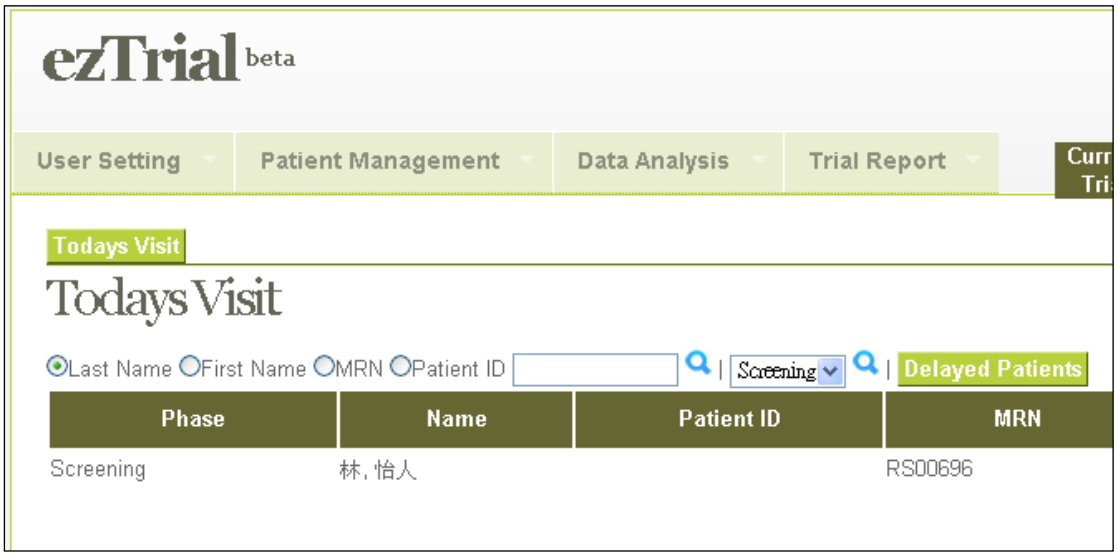
Withdraw Patient:

By selecting **[Withdraw Patient]** under **[Patient Maintenance]**, the system will display a list of all withdrawn patients.

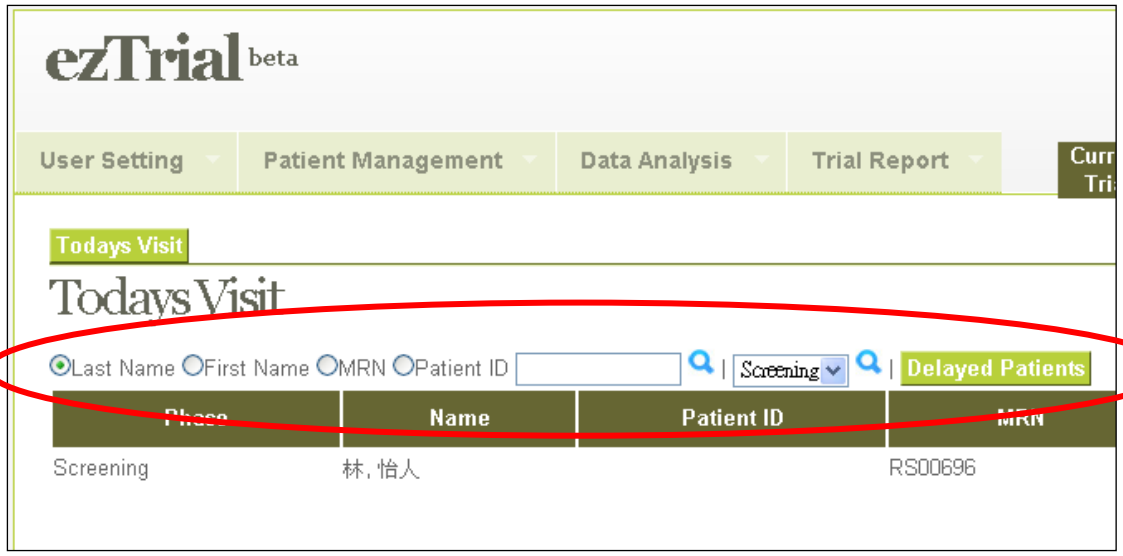
You can edit the Withdrawn Status and Withdrawn Comment by clicking the **[Edit]** button.

2.2.2 Patient Record

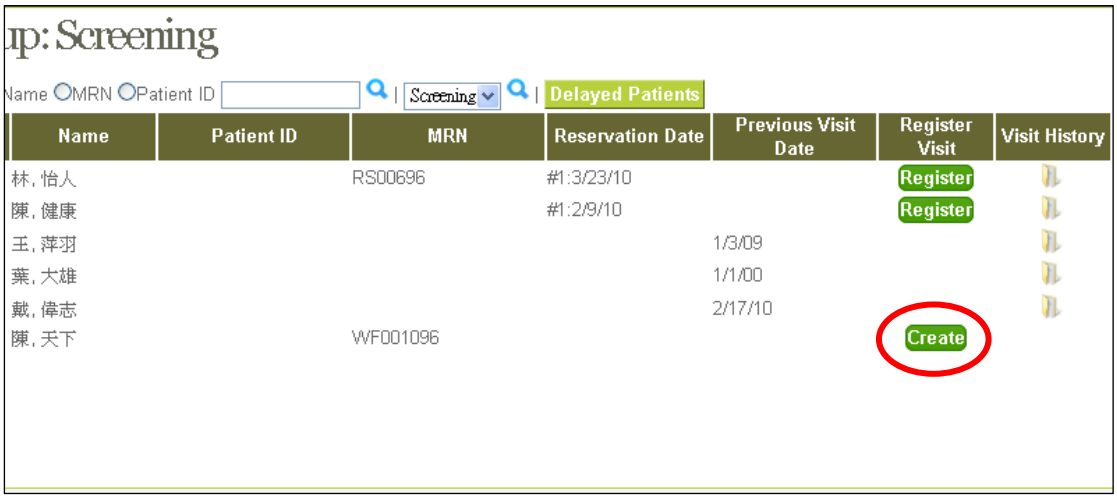
By selecting **[Patient Record]**, the system will display a list of patients with appointments today. .



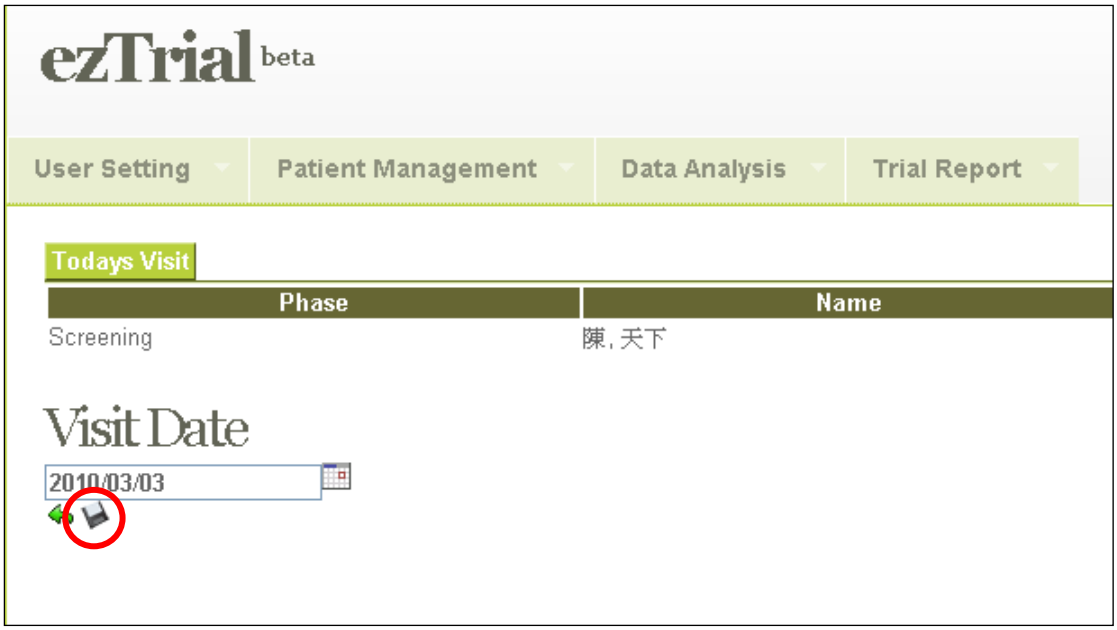
To find a patient, simply input his/her first name, last name, medical record number or I.D. and also select the phase.



For a patient in a new phase, click **[Create Visit]** to schedule a visit.

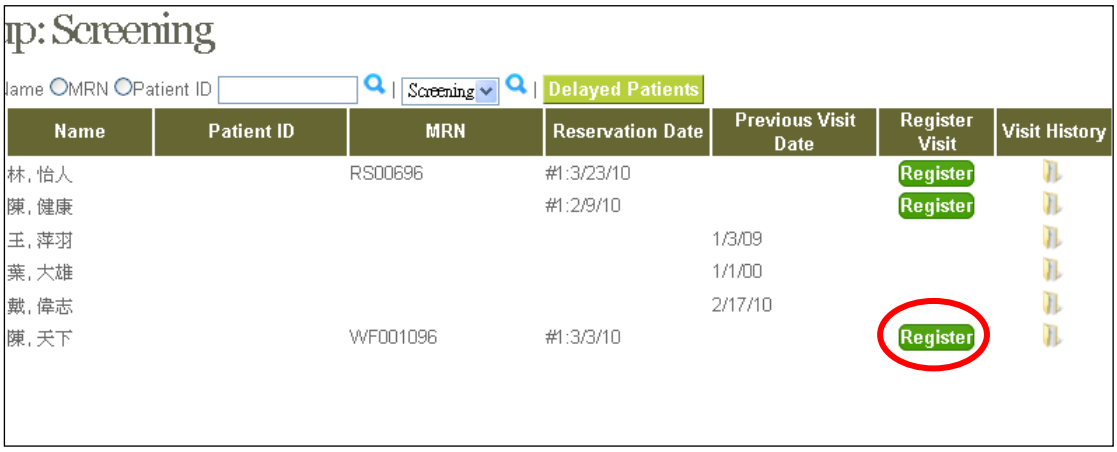


When the Schedule Visit screen is displayed, input the visit date or click the calendar icon to choose a date.

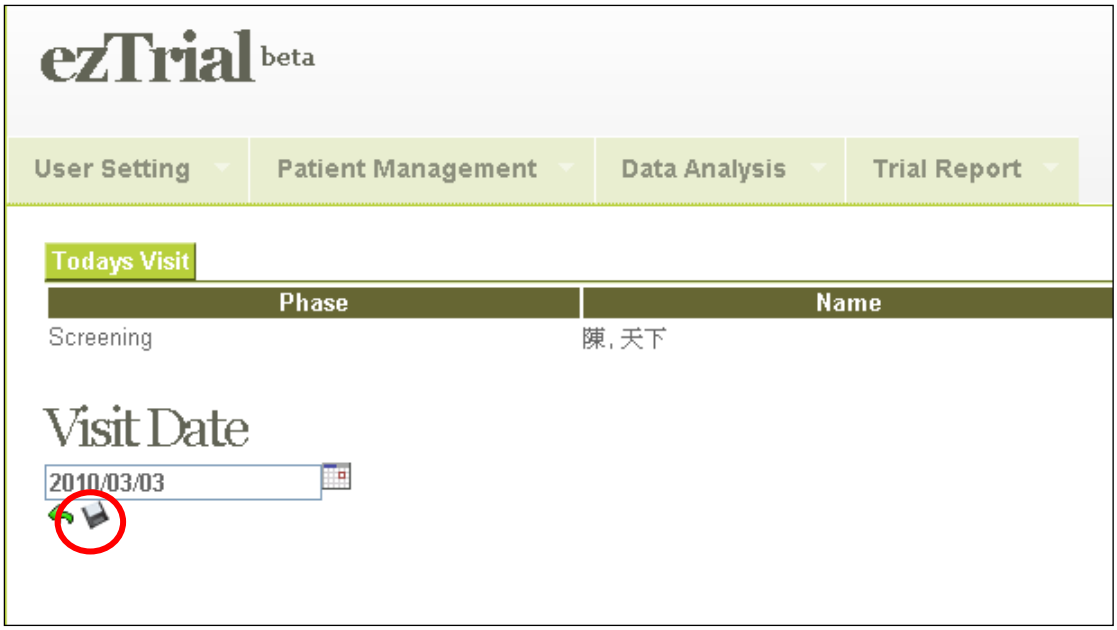


After selecting the appointment date, click **[Save]**. The system will then redirect you to Today's Visit page.

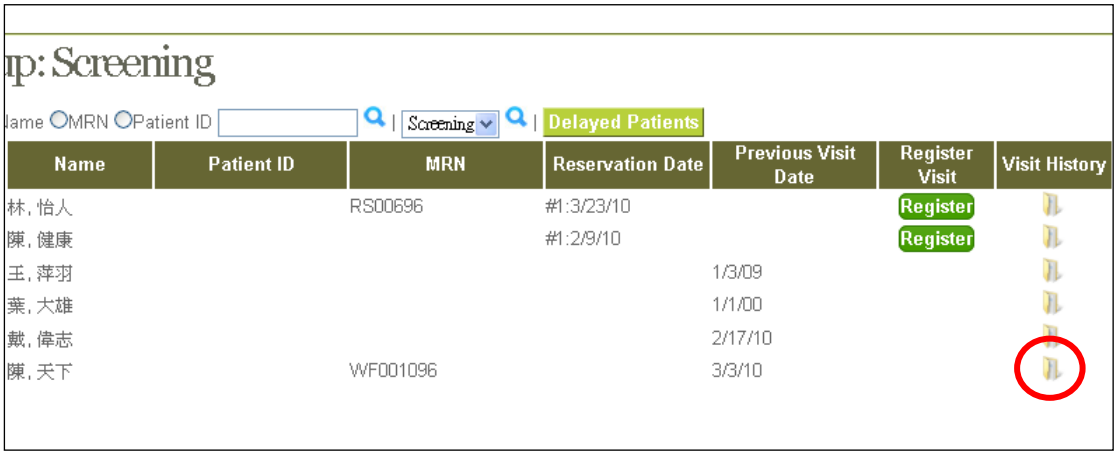
You can record a patient's arrival date by clicking on **[Register]**.



Select the patient's arrival date and click **[Save]**. The system will then redirect you to Today's Visit page.

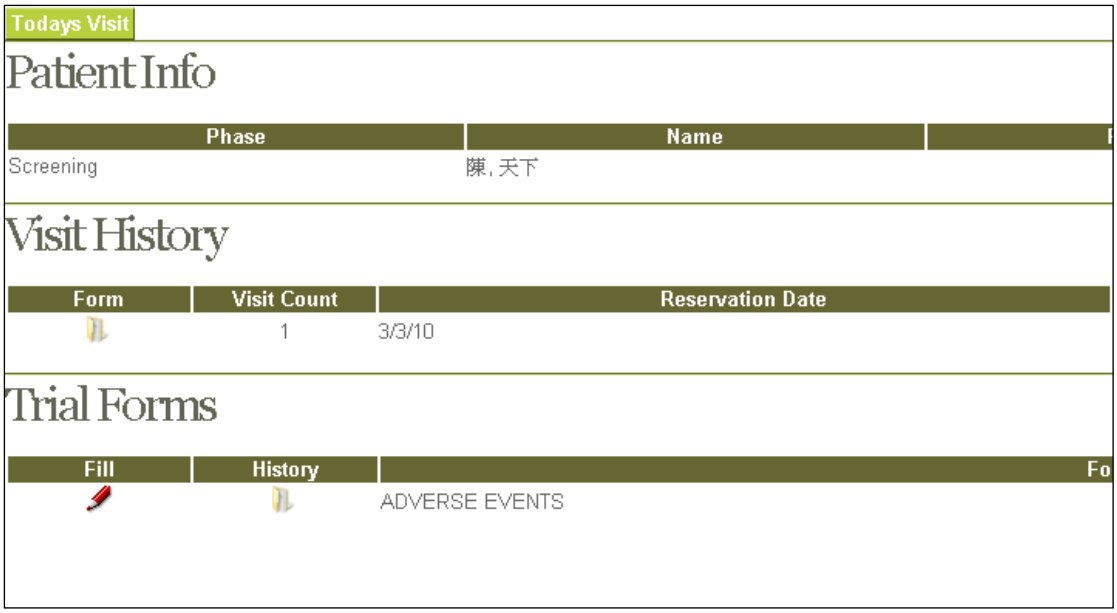


After the visit date has been saved, the system will automatically generate the next appointment according to the schedule if applicable. Click the **[Visit History]** button to see the patient's visit details and records.



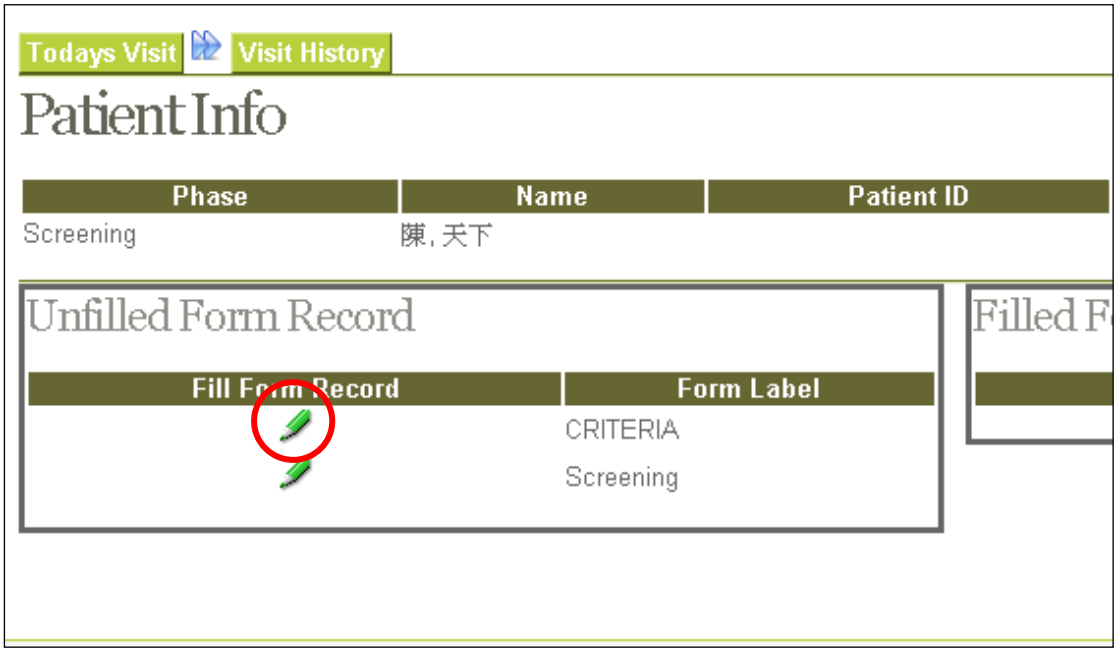
The patient's visit history page is divided into patient information, visit history, and trial forms.

The patient information part shows the patient's basic data, such as the current phase, name, case number and MRN.

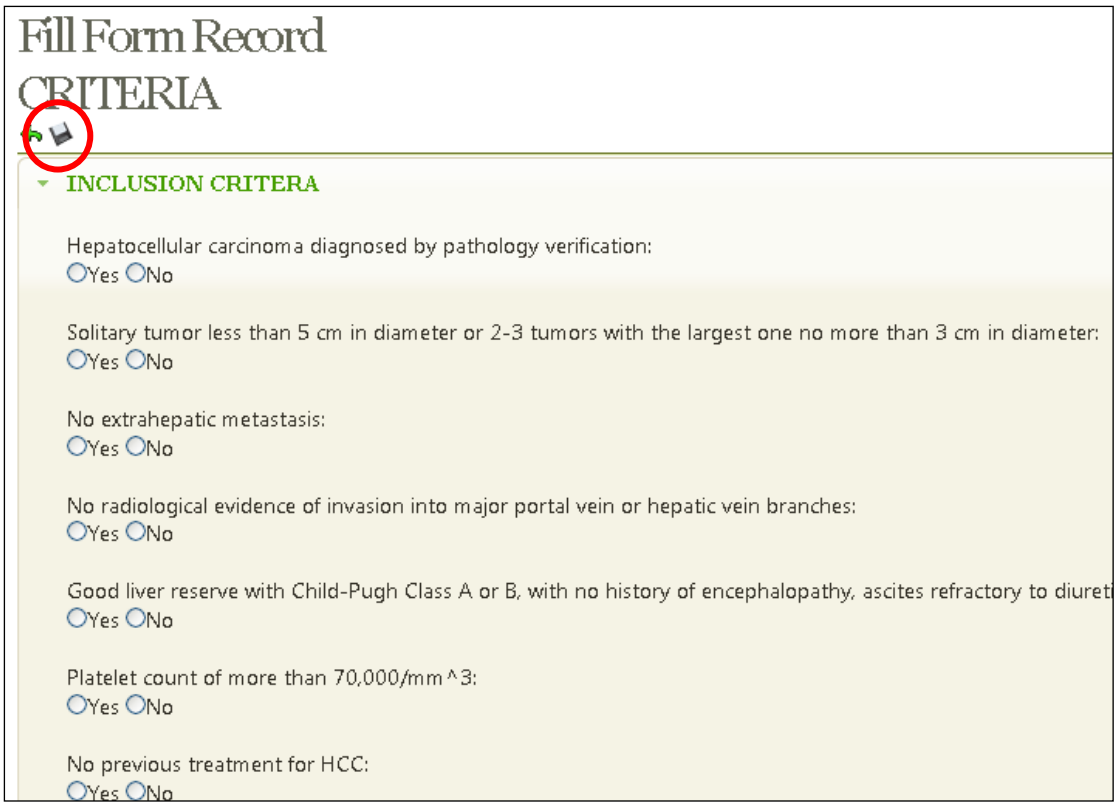


The visit history part shows the patient's visit records, including dates and times.

To complete the appropriate visit forms, click on the form button in the visit history section. New forms will be listed on the left-hand side of the screen, and saved forms will be listed on the right-hand side.

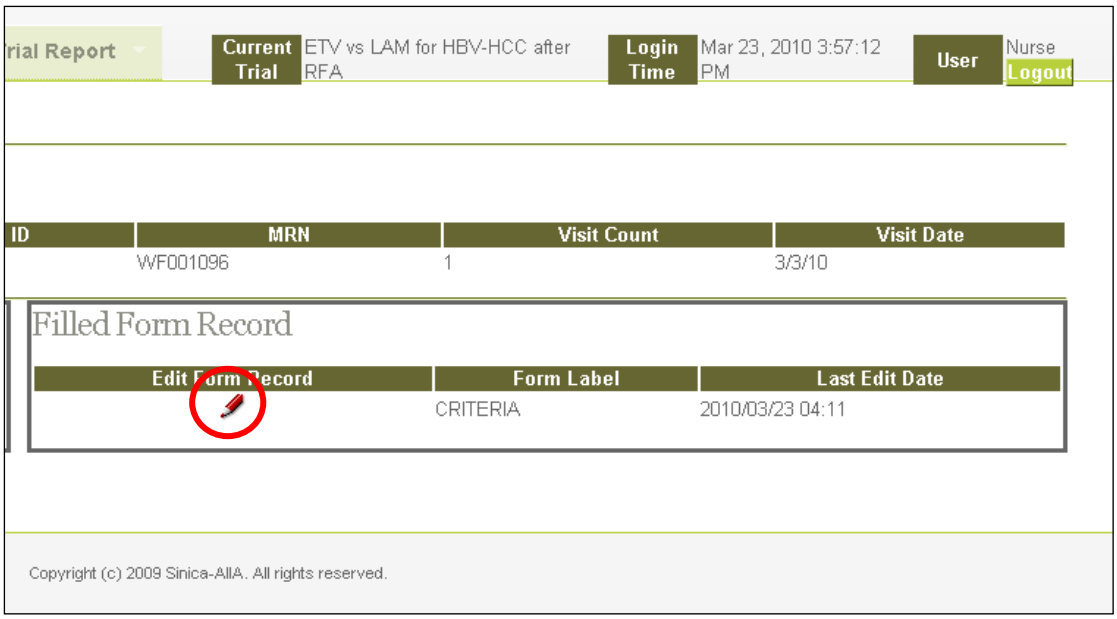


Click the icon of the form you wish to complete. We provide an example of [CRITERIA] below.

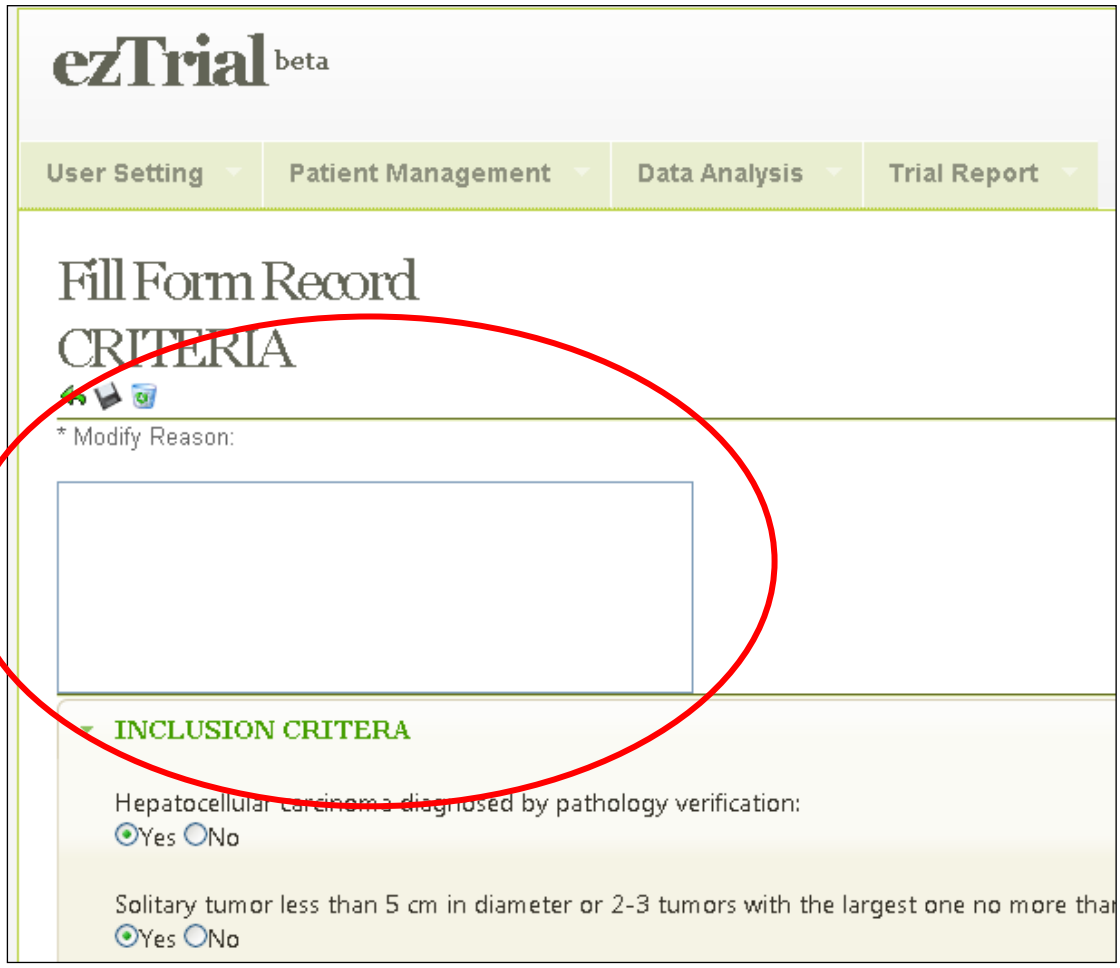


Different sections of the form can be displayed. Click on the section you wish to complete and the section will be enlarged. After entering the data, click **[Save]**. The system will insure the data is valid, save it, and redirect you to the visit history page; otherwise, the system will display an error message in red and return to the editing page.

If you wish to modify a form, click the **[Edit]** button in front of the appropriate form.



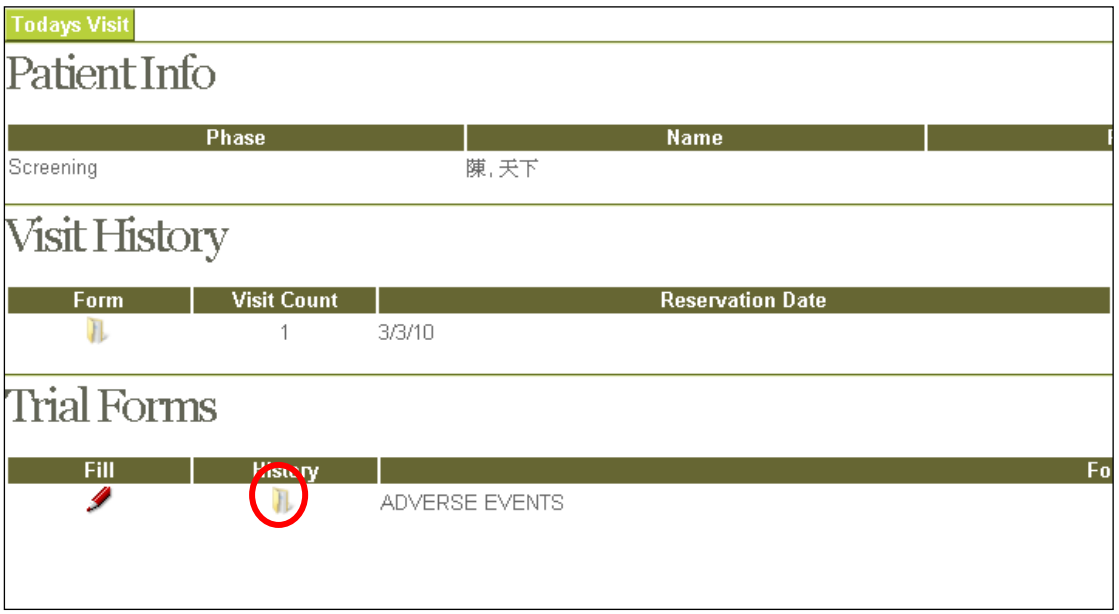
The reason for modification must be provided.

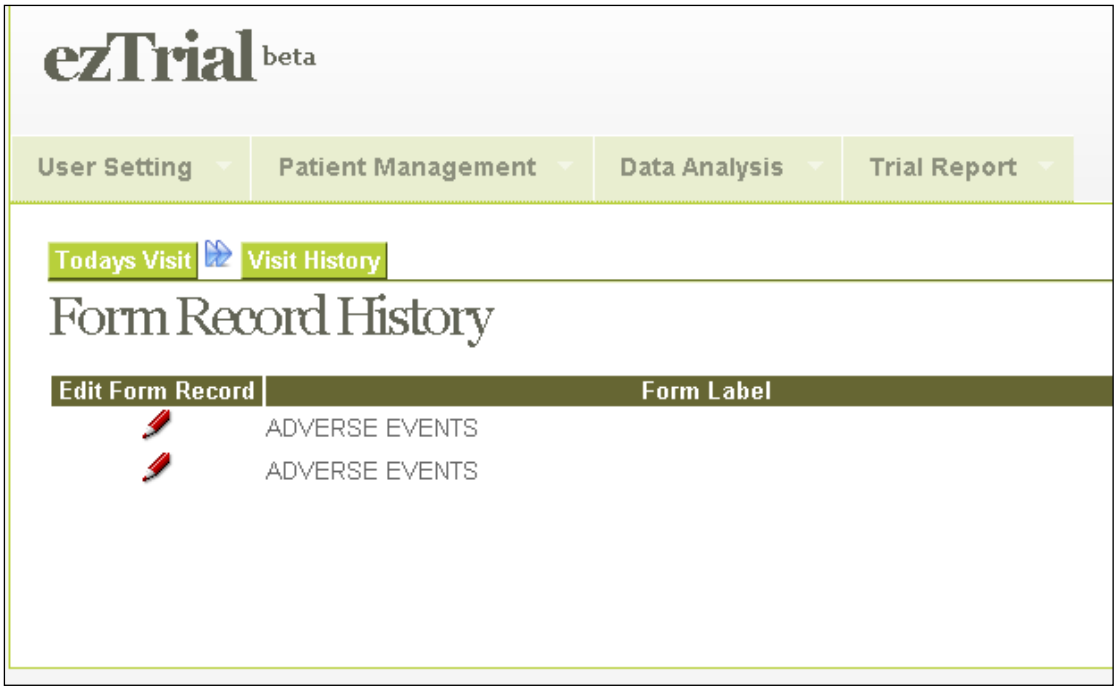


The trial forms section shows the available forms used to record the patient's data. New information can be added to a form at any time. This

page shows an example of [ADVERSE EVENTS].

After saving the information, click **[History]** to check the Form Record History or make modifications.



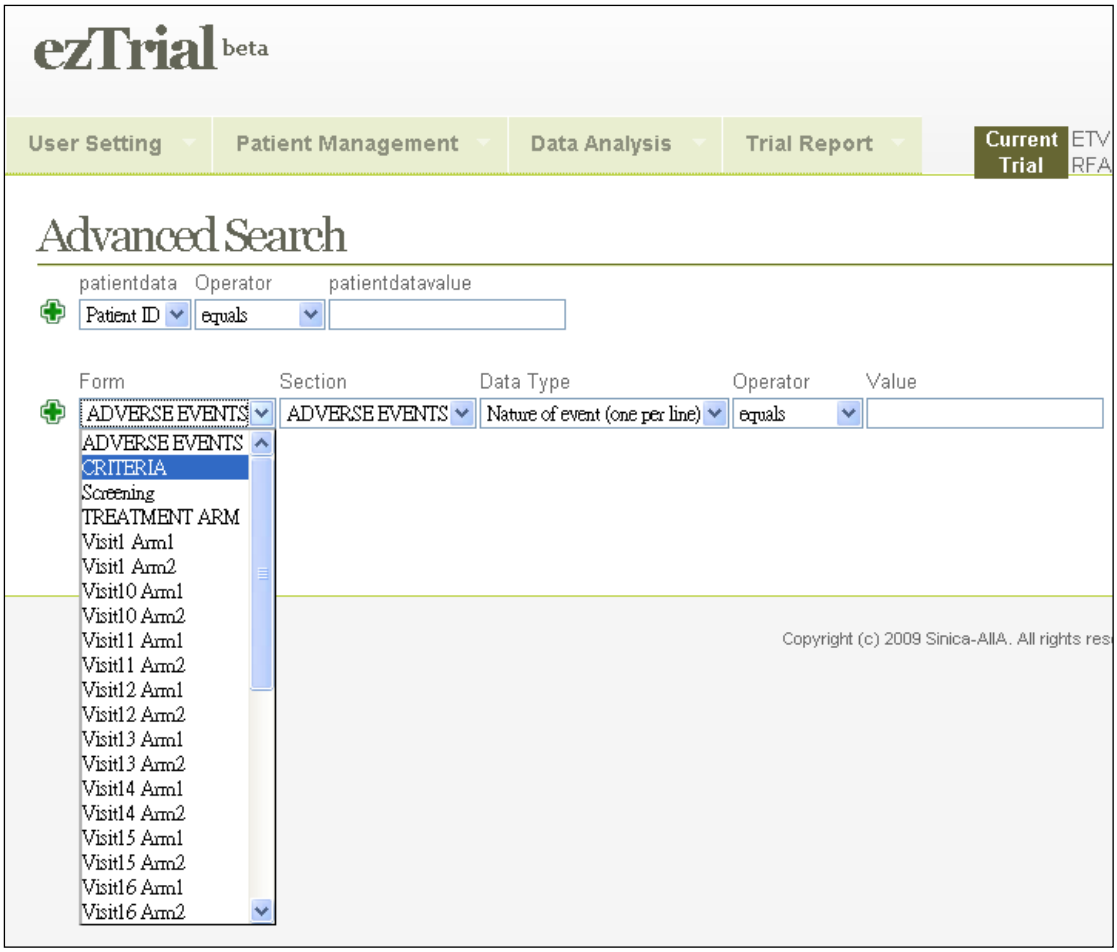


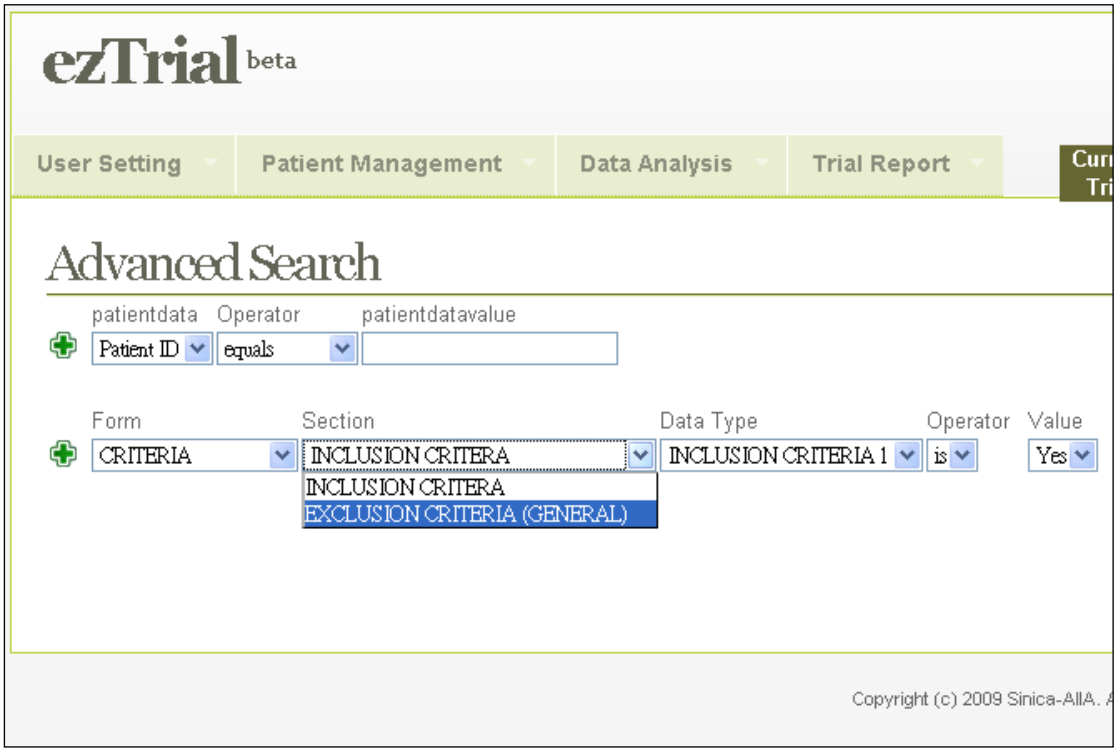
2.3 Data Analysis

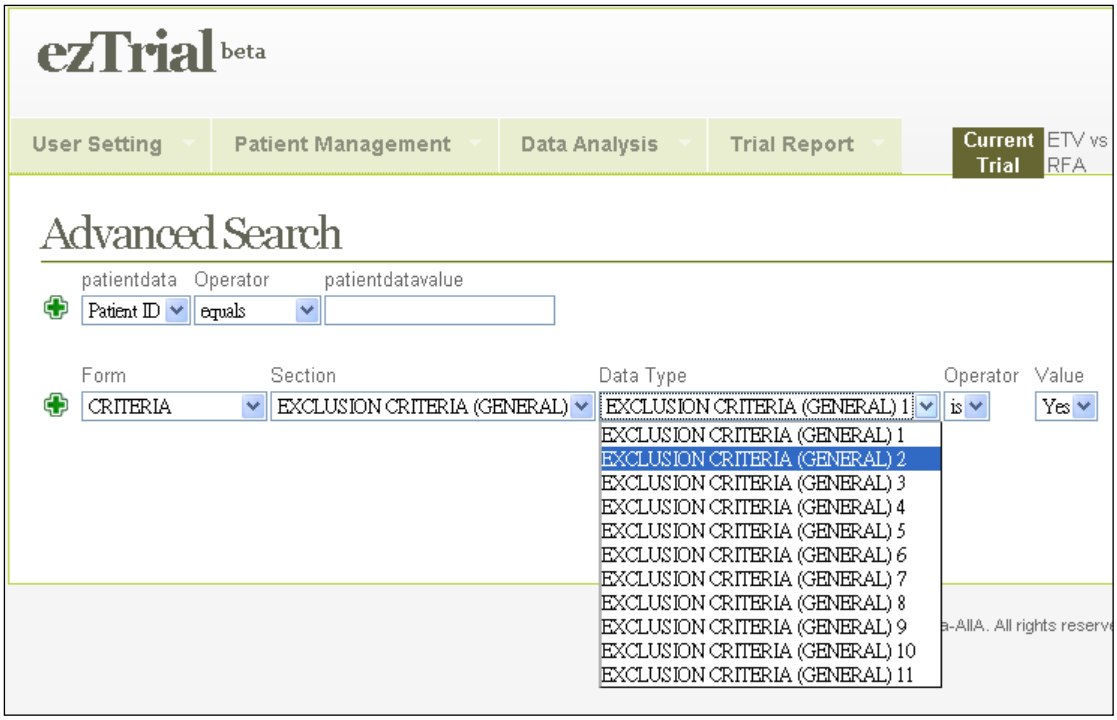
2.3.1 Advanced Search

This feature allows you to select a group of patients and export their data. The advanced search form consists of a set of drop-down menus. The top section displays the patients' information, and the bottom section shows the form record.

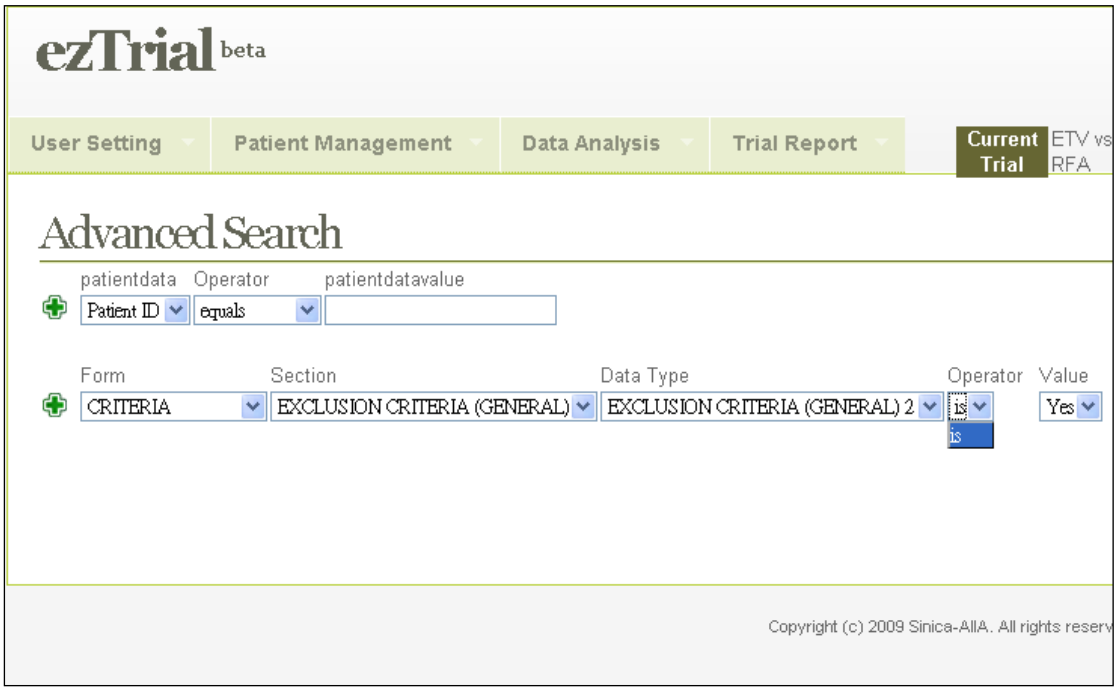
After you make the first selection, a list of search criteria will be displayed in the second menu. The third menu displays another dynamic list of search criteria based on those in the second menu.


ezTrial beta
User Setting
Patient Management
Data Analysis
Trial Report
Current Trial
ETV
RFA
Advanced Search
patientdata
Operator
patientdatavalue
Patient ID
equals
Form
Section
Data Type
Operator
Value
ADVERSE EVENTS
ADVERSE EVENTS
Nature of event (one per line)
equals
ADVERSE EVENTS
CRITERIA
Screening
TREATMENT ARM
Visit1 Arm1
Visit1 Arm2
Visit10 Arm1
Visit10 Arm2
Visit11 Arm1
Visit11 Arm2
Visit12 Arm1
Visit12 Arm2
Visit13 Arm1
Visit13 Arm2
Visit14 Arm1
Visit14 Arm2
Visit15 Arm1
Visit15 Arm2
Visit16 Arm1
Visit16 Arm2
Copyright (c) 2009 Sinica-AIIA. All rights res

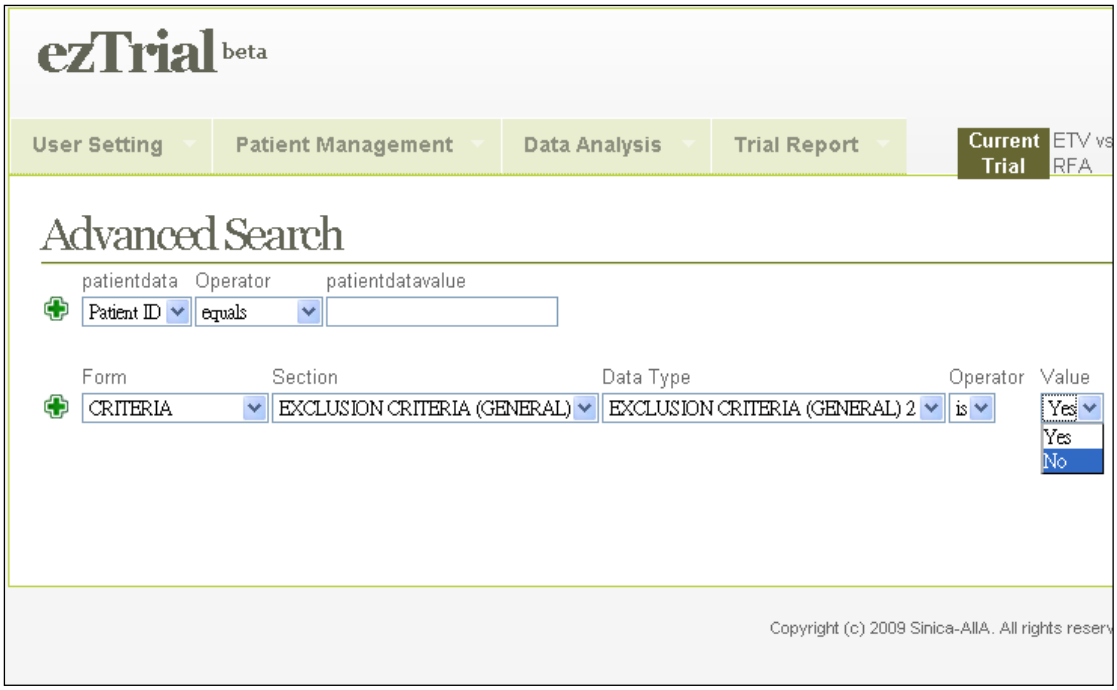

ezTrial beta
User Setting
Patient Management
Data Analysis
Trial Report
Advanced Search
patientdata
Operator
patientdatavalue
Patient ID
equals
Form
Section
Data Type
Operator
Value
CRITERIA
INCLUSION CRITERA
INCLUSION CRITERIA 1
is
Yes
INCLUSION CRITERA
EXCLUSION CRITERIA (GENERAL)
Copyright (c) 2009 Sinica-AIIA.



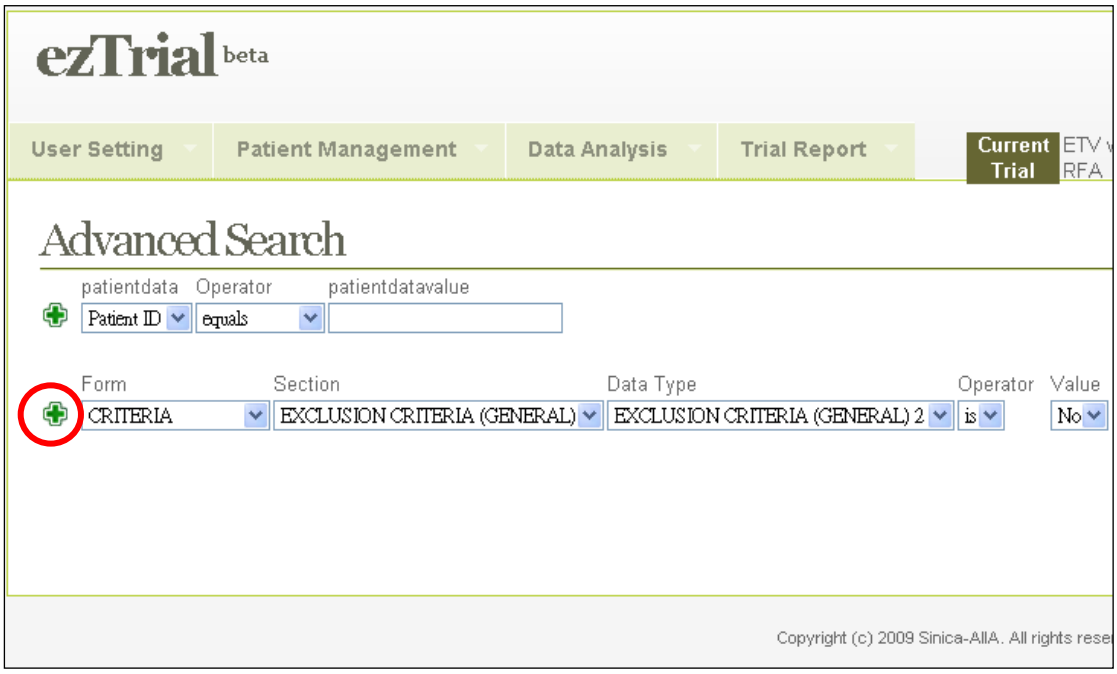
The selections available in the fourth menu depend on the variable chosen in the third menu, but may contain “equals”, “is not equal to”, “starts with”, “ends with”, and “contains” (see the following page):



In this example, we query the database to search for all patients EXCLUSION CRITERIA (GENERAL) 2 is “No”.

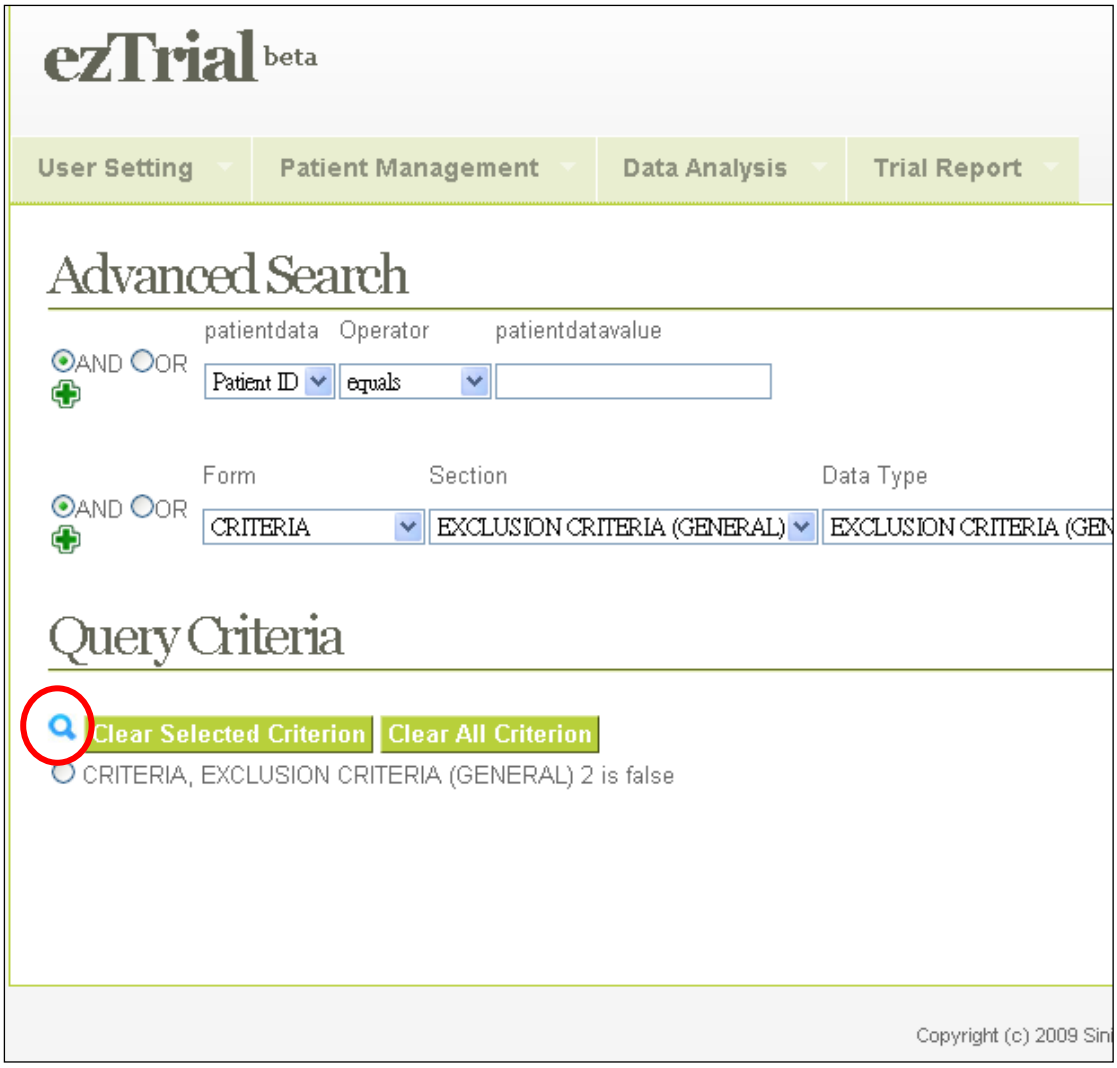


After finalizing a query criterion, click **[Add Criterion]**.

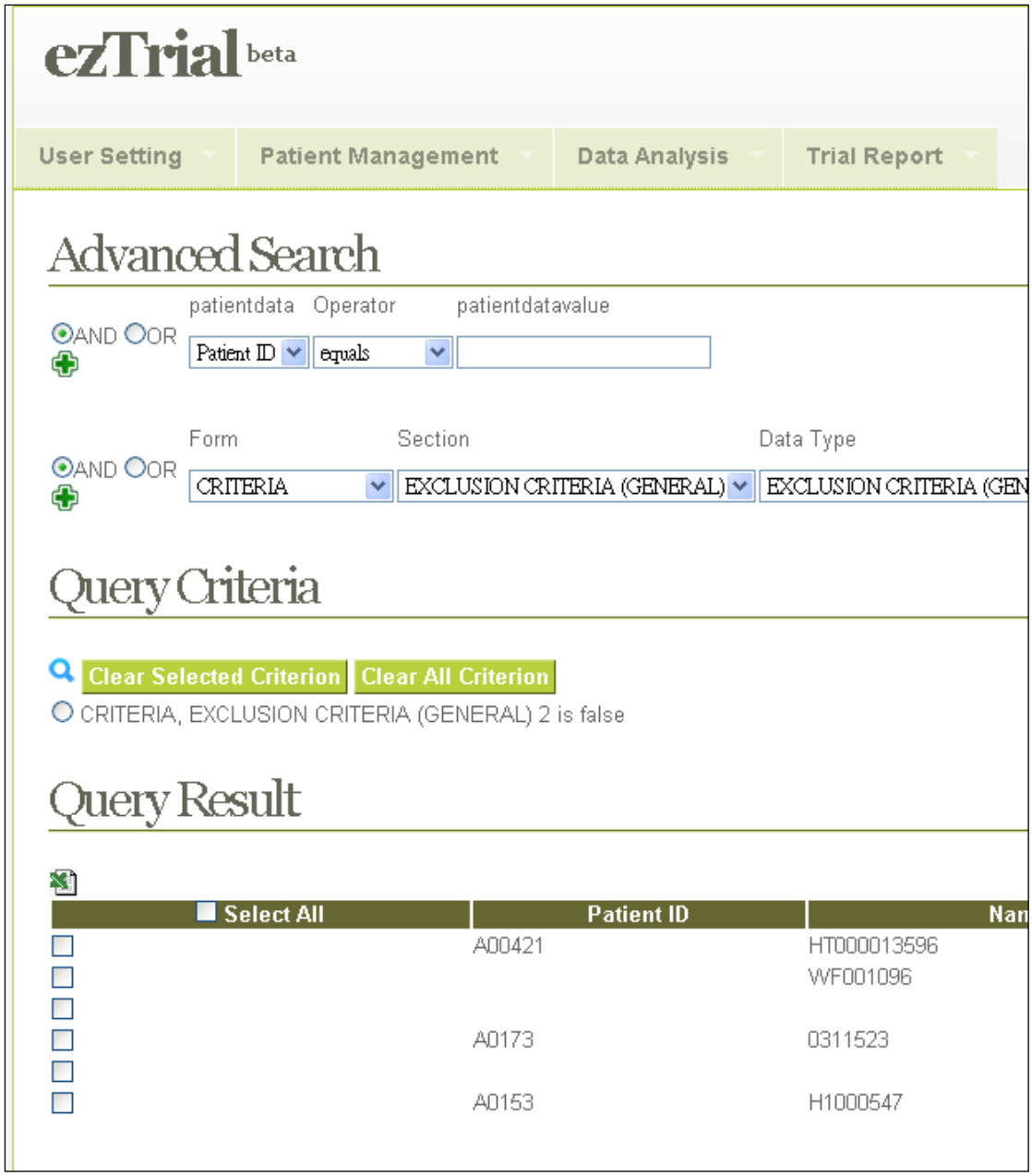


You can add more than one criterion.

After finalizing the query, click on the **[Search]** button.



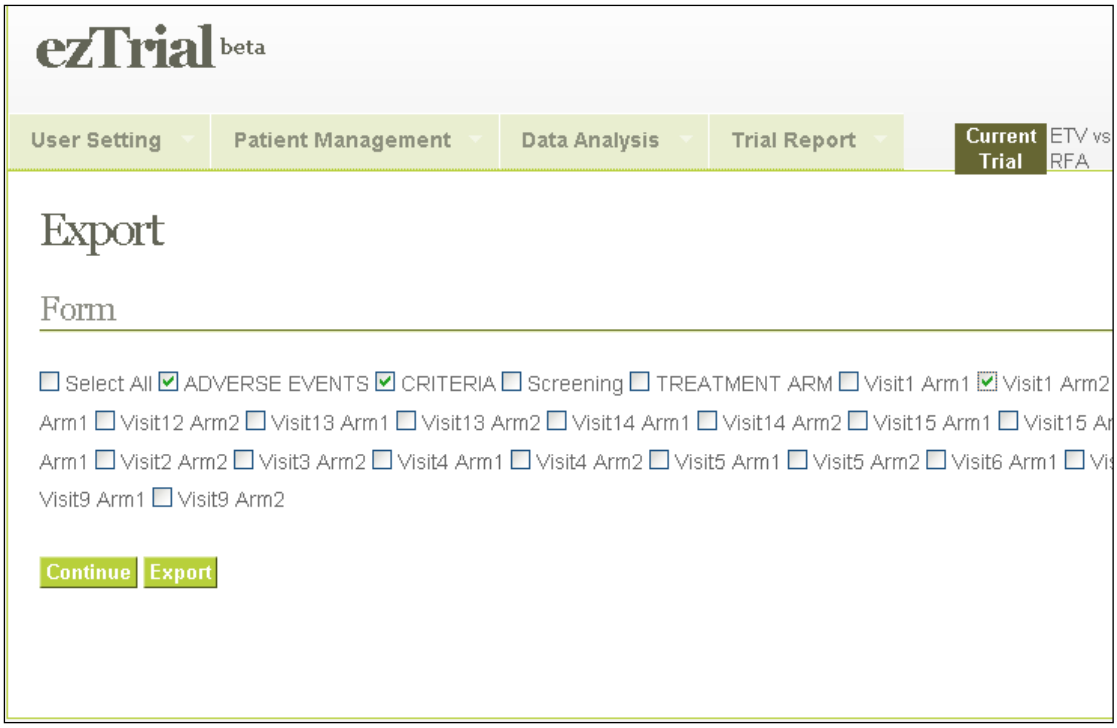
A list of records that match your specifications will be displayed.



Users also have the option of exporting all patient records matching the selected criteria to an Excel spreadsheet by clicking **[Export]**.

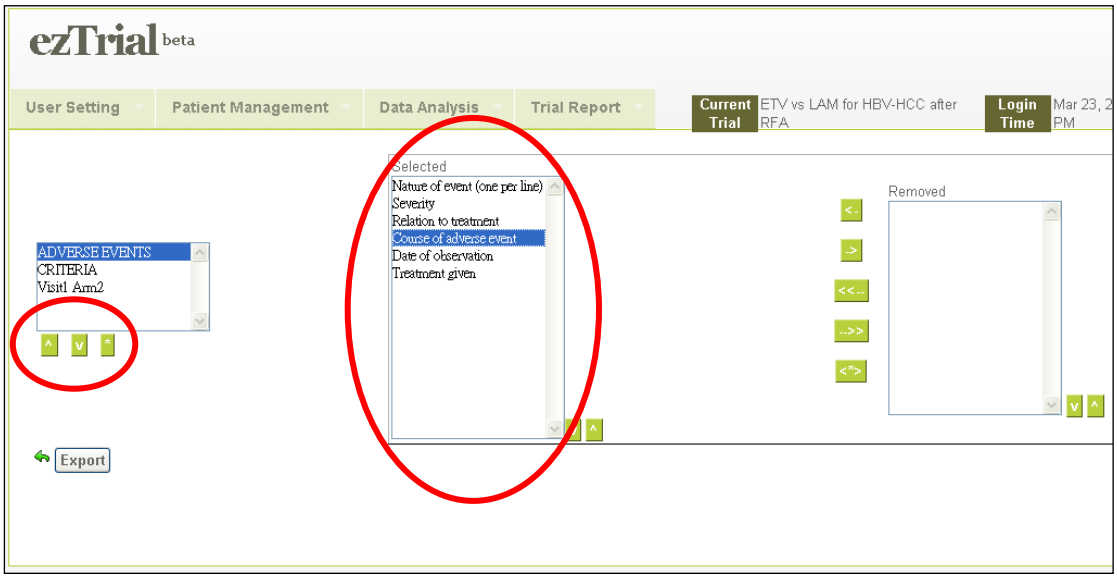
2.3.2 Export Data

The Export Data function allows you to export form data of interest. In this example, CRITERIA, Visit1 Arm2 and ADVERSE EVENTS form are selected for export.



Click **[Export]** to export data.

Click **[Continue]** to select further, form data points.



Use the - Remove Data Points function to remove data points that you do not want to export. After completing and clicking the **[Export]** button, you will be given the option to either open the form directly or save it to your computer. If you choose to open the form directly, it will be displayed in your browser window. After reviewing the data, simply click the browser's back button to return to the system.