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Clinical Study Process Flow Diagram
Navigation

Getting Started

To log-in, go to: https://jefftrial.tjh.tju.edu

JeffTrial Login Screen

The JeffTrial User ID and Password will be your TJU campus key and password. Your JeffTrial password will be automatically updated when you update your TJU password.

JeffTrial uses secondary browser windows to display various selection choices. Popup blockers may prevent these browser windows from displaying, therefore, popup windows must be allowed in order for JeffTrial to display the secondary browser windows. Contact your ADMIN for assistance.

It is recommended that users avoid using the browser back button while working in JeffTrial. Instead, use the tabs or menu links within JeffTrial to navigate.

For training purposes, please use the training environment: https://jefftrial-train.tjh.tju.edu
User Roles

Access to the various functions of JeffTrial is determined by assigned user roles (i.e. PI, PC, REG, etc.). These roles do not necessarily correspond to your role within TJU. If you are assigned more than one user role, you may switch between roles by selecting from either the drop down list at the top of the page next to your name or within the My Profile link at the top right of the page.

User Role Designation

My Profile

In addition to selecting your default role, you can change the theme color of JeffTrial within My Profile.

My Profile

Menu Bar

The Menu Bar consists of multiple menus that are always accessible. Only those menus that apply to the role of the user will display.

JeffTrial Menu Bar

Header

The header provides read only summary information for the protocol (i.e. PI, Protocol Target Accrual, Protocol Status, etc.) and is consistent across the group of related pages that are associated with the menu bar.

Header (PC Console)
Horizontal and Vertical Tabs

Vertical tabs on the left side of the page allow for easy navigation between logically organized subsets of information. Vertical tabs with an arrow contain additional horizontal tabs.

Horizontal tabs, located below the header, are used to display different pages related to the specific vertical tab.

Find-as-you-type Fields

Find-as-you-type fields have a down arrow that provides a list from which you may select. Also as data is entered into the field, the results list is narrowed.
Update, Submit, Close, and Add Buttons

[Update] – If at any point you cannot edit any of the fields, look for an update button towards the bottom right of the page. If you cannot find the update button, then it is likely that you do not have the correct privilege to update any of the fields within the page. If you would like to suggest changes to these privileges, please complete a JeffTrial service request (more information on page 11).

[Submit] – You must hit the submit button near the bottom right of the page if you wish to save any changes made to the page.

[Close] – Hitting the close button will either allow you to exit the current page or change it into a view-only mode.

[Add] – The add button allows users to add pertinent information (i.e. staff members, study drugs, sponsors, etc.) within the page of its location. This WILL NOT save changes made in other fields of the same page.

Reference Codes / Libraries

Reference codes define lists of choices when entering data. Some are industry standard, some are defined by the vendor, and others are defined by TJU. Libraries are preset templates of reference codes, forms, notifications, etc. If you would like to suggest any changes to the reference codes or libraries, please complete a JeffTrial service request.

Date Widget Shortcuts

<table>
<thead>
<tr>
<th>Shortcut</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>t</td>
<td>Today’s date</td>
</tr>
<tr>
<td>t ± #</td>
<td>Today’s date plus or minus the number of days entered</td>
</tr>
<tr>
<td>w ± #</td>
<td>Today’s date plus or minus the number of weeks entered</td>
</tr>
<tr>
<td>m ± #</td>
<td>Today’s date plus or minus the number of months entered</td>
</tr>
<tr>
<td>y ± #</td>
<td>Today’s date plus or minus the number of years entered</td>
</tr>
<tr>
<td>mb ± #</td>
<td>Month beginning (can be used alone or with ± # of months)</td>
</tr>
<tr>
<td>me ± #</td>
<td>Month end (can be used alone or with ± # of months)</td>
</tr>
<tr>
<td>yb ± #</td>
<td>Year beginning (can be used alone or with ± # of months)</td>
</tr>
<tr>
<td>ye ± #</td>
<td>Year end (can be used alone or with ± # of months)</td>
</tr>
</tbody>
</table>
Homescreen

Home Screen and Widgets

After logging into JeffTrial, you are presented with your Home screen, also known as your dashboard:

![Home Screen Image]

The Home screen may be customized to display widgets. A widget is a personalized display of JeffTrial data, and contains links allowing you to quickly access that data. Widgets will only display data that you have the appropriate privileges to view.

JeffTrial provides widgets for Protocols, Subjects, SAEs, Reports, Registrations, and saved Protocol Searches. Depending upon your needs, you may add one or more of these widgets to your Home screen.

Bookmarks

Some widgets display bookmarked protocols and subjects. Bookmarking is a simple way for you to indicate the data that is most important to you.

To bookmark a protocol, display the protocol in the PC Console, then click the star icon in the upper left corner:

![Protocol Bookmark Image]

When the Protocol is bookmarked, the star will be an amber color.

To remove a bookmark from a protocol, click the amber star. The icon will turn white. Bookmarks may also be removed via the Bookmarks tab that is displayed when configuring widgets (see the Configuring Widgets section below).
To manage bookmarks for a subject, display the subject in the Subject Console and follow the same procedures.

**Adding, Positioning, and Removing Widgets**

To begin your Home screen customization, you must display your Home screen by clicking on the Home link found at the upper right of all JeffTrial pages.

When viewing your Home screen, the ‘gear’ icon is shown next to the Home link:

![Home screen with gear icon](image)

Clicking the ‘gear’ icon launches the Home Screen Configuration page. The Widgets vertical tab will be highlighted, and your widget configuration will be shown in the main body of the page. Here is an example:

![Home Screen Configuration page](image)

Widgets listed in the white boxes display on the left (column 1) or right (column 2) of the Home screen.Widgets listed in the table at the bottom have not been selected for display.

To add an unselected widget to your Home screen, select its corresponding Add checkbox and click the [Save] button. The widget will disappear from the table and display in either ‘column 1’ or ‘column 2’.

After a widget is added to the Home screen, additional configuration may be required before the widget displays data. This is discussed in the **Configuring Widgets** section found later in this document.

A widget’s position on the Home screen can be changed by clicking the widget name within one of the columns and using the green arrows to modify the Home screen layout:
To remove a widget from your Home screen, click the widget name shown in one of the columns, then click the [Delete] button that appears.

Clicking on the Home link will return you to the Home screen:

At the upper right of every widget is the delete icon. You may use this icon to remove the widget from your Home screen.
Configuring Widgets

When you configure a widget, you specify which data you wish to see. The Protocols, Subjects, SAEs, and Registration widgets will not display JeffTrial data until they are configured. (The Saved Searches and Registration widgets are preconfigured.)

Widget configuration is done via the gear icon found at the upper right of the widget. Clicking the gear icon displays a pop-up that contains one or more tabs:

- The criteria used to select data for the widget is specified in the Watch tab. For information on a widget's Watch tab, see the discussion of the widget found later in this document.
- The Fields tab is used to specify which fields of selected data to display in the widget. Here is the Fields tab for the Protocol widget:

<table>
<thead>
<tr>
<th>Fields</th>
<th>Description</th>
<th>Dashboard</th>
<th>Expanded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Protocol No.</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Short Title</td>
<td>Short Title</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Status</td>
<td>RC Status</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>RC Acc</td>
<td>RC Accrual</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>VA Acc</td>
<td>VA Accrual</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>AF Acc</td>
<td>AF Accrual</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Accrual</td>
<td>Total Accrual</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Role</td>
<td>My protocol staff role</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Maximum item display</td>
<td>30</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

- Use the checkboxes to specify which fields to display. Enter a value into a “Maximum item display” field to limit how many items are listed in the widget. (The number of items displayed in the Dashboard report will affect Home screen performance.) If there are more items than what is listed in this maximum field, they will not display in the widget.
- Note that there are two columns of checkboxes. The Dashboard column refers to the widget as shown on the Home screen. The Expanded column refers to a pop-up display that is launched by clicking the widget's icon.
- Be sure to save your choices by clicking the [Save] button.
The Protocols, Subjects, and SAEs widgets can display bookmarked protocols and subjects. When configuring these widgets, one or more Bookmarks tabs are provided. The Bookmarks [Protocol] tab displays all the protocols you have bookmarked. The Bookmarks [Subject] tab displays all the subjects you have bookmarked.

Bookmarks tabs are used to remove bookmarks from protocols or subjects. Here is the Bookmarks [Protocol] tab for the Protocol widget:

- Selecting a Remove checkbox and clicking the [Save] button will remove the corresponding bookmark.
Submitting Requests for JeffTrial

All requests for technical assistance, addition of data points or checklists, and suggestions should be made via the KCC Service Request website at:

https://black.kcc.tju.edu/isrticket/

*A hyperlink to this website is also provided on the IRB homepage in the navigation bar on the left side of the screen.

Alternatively, you can reach the service request website from the Jefferson homepage or the KCC homepage via the following click paths:

http://www.jefferson.edu/ → Jefferson Kimmel Cancer Center → KCC Intranet → Service Request

http://www.kimmelcancercenter.org/ → KCC Intranet → Service Request

Below is a screenshot of what the page looks like:

*When completing the service request, be sure to select “JeffTrial” under request type.
Please follow the guideline when submitting a JeffTrial service request:

**Staff Access**

1. When a new employee starts, their manager should determine what JeffTrial user role is needed and submit the following required information in the comments section:
   a. Campus key
   b. Email address
   c. Department/Division:
   d. JeffTrial system user role(s) are:
      - Protocol Coordinator (PC) – Manages the overall protocol (study) including subjects
      - Regulatory Coordinator (REG) – Responsible for the regulatory process and documents particularly in relation to the IRB process
      - Principal Investigator (PI) – View only role and allows the user to see information on the studies they are assigned to

2. The JeffTrial Administrator will set up the user in JeffTrial

3. Before the user can access and use JeffTrial, they must be trained by a JeffTrial Superuser.

**Drugs/Devices/Institutions/Sponsors/etc.**

1. When a REG or PC is entering protocol information, the process is to look for the Drug, Device, Institution or Sponsor in the existing pull down lists.

2. If the information is not found in JeffTrial, a request should be submitted to add it. The request should be submitted with the appropriate information.

3. The ADMIN will also verify that the information is not currently in JeffTrial by doing a search. Once verified the information will added and you will be notified of the change.

*Please note, you will receive a ticket number for your request which will allow you to track its progress.*
PART I: Protocol Creation

JeffTrial (OnCore®) is a Clinical Trials Management System used here at Thomas Jefferson University. It is used for protocol management, calendar and financial management, as well as subject management. Depending on your responsibilities, you will be asked to fulfill any of these duties to ensure that your clinical trial is managed properly.

In this section, you will learn how to create a protocol and prepare it for both calendar creation and IRB submission.

Entering New Protocols

The process of creating a new protocol within JeffTrial begins in the PC Console. The PC Console can be found under “Protocols”, located in the menu bar. When the PC Console is opened, the “New Protocol” vertical tab is located at the bottom left side of the page, as shown below:

Homepage:  
Protocol  PC Console, New Protocol (Vertical Tab):
The New Protocol Page is where you would enter basic information about the protocol. The following is a screenshot preview of the New Protocol Page:

**New Protocol**

**Protocol → PC Console, New Protocol (Vertical Tab):**

When starting a new protocol, you must enter (at minimum) the following required fields shown on the New Protocol page, followed by the [Submit] button (Required fields have an *):

-Please note, all of the information can be changed at a later time.

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
</table>
| Protocol No.  | This number is auto-generated by JeffTrial  
*Be sure to keep track of this number during the initial stage of protocol entry as it is the only number to identify the study prior to receiving an IRB control number* |
| Library       | Choose between "Oncology" or "Non-Oncology"                                                                                                   |
| Department    | This list corresponds to the departments at TJU (if you do not see your department, please contact the administrator)                        |
| Title         | Full title of the study                                                                                                                       |
| Age           | Options are ‘Adults’, ‘Children’, or ‘Both’                                                                                                    |
Investigator Initiated Protocol | Indicate whether it is an investigator initiated study or not
--- | ---
Protocol Type | 
Epidemiological | Studies that involve no intervention or alteration in the status of the participants (i.e. surveillance, risk assessment, outcome, environmental, and behavioral studies)
Genetic | Studies using specimens to assess clinical outcomes, response to therapies, etc.
Interventional | Clinical Research Category in which individuals are assigned by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, therapeutic, behavioral or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.
Observational | Clinical Research Category that involves no intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.
Registry | An organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes.
Investigational Drug | Options are ‘Yes, ‘No’, or ‘N/A’
Investigational Device | Options are ‘Yes, ‘No’, or ‘N/A’
Protocol Target Accrual* | Enter the number of subjects to accrue for the protocol, across all participating institutions (TJU and affiliates). This DOES NOT refer to the national accrual goal.
RC Total Accrual Goal (Upper)* | How many subjects TJU alone plan to enroll for this protocol (this number could be the same as Protocol Target Accrual if TJU is the only site of enrollment)
Accrual Duration (Months)* | Indicates the estimated number of subjects that will accrue at the Affiliates running the protocol
Primary Completion Date | Unless you know the exact date of study completion, please check off the “Anticipated” option
| *Since this information may be unknown at the time of completing this page, simply type in ‘y+5’ to indicate 5 years from today.

*If this information is not yet known, check the Not Applicable box for now
Main (Vertical Tab)

After completing the New Protocol page, you will be taken to the Details page of the Main vertical tab. The Main vertical tab contains several different horizontal tabs where you can further enter basic protocol information. The horizontal tabs in left to right order are Details, Management, Staff, Sponsor, IND/IDE, and ClinicalTrials.gov.

Details

The Details horizontal tab is where you can update/review the protocol detail information. You can see in the screenshot below, the Details page contains all of the initial information completed on the New Protocol page:

Protocol → PC Console → Main (Vertical Tab) → Details (Horizontal Tab)
Once additional information is available, you will be responsible for completing as many fields as possible on this page. Refer to the following guide for completion of this page:

<table>
<thead>
<tr>
<th><strong>Field</strong></th>
<th><strong>Description</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>*Department</td>
<td>The ‘Department’ selected should represent the institutional funding body for the study. Fiduciary reporting is available based upon this.</td>
</tr>
<tr>
<td>NCT Number</td>
<td>The protocol identifier assigned by clinicaltrials.gov</td>
</tr>
<tr>
<td>*Title</td>
<td>The full title of the protocol.</td>
</tr>
<tr>
<td>Short Title</td>
<td>A short title created for the protocol.</td>
</tr>
<tr>
<td>Objectives</td>
<td>A 2-3 sentence lay language summary of the study objectives.</td>
</tr>
<tr>
<td>Phase</td>
<td>The phase for the protocol.</td>
</tr>
<tr>
<td>Scope</td>
<td>Indicates the enrollment scope. Typically, ‘local’ indicates the trial will only be open for the research center, ‘national’ indicates a multi-institutional trial. This field is capture only and does not indicate scope for Summary 4 reporting or any other JeffTrial functionality.</td>
</tr>
<tr>
<td>*Age</td>
<td>Indicates whether subjects are adults, children or both.</td>
</tr>
<tr>
<td>Consent at Age of Majority</td>
<td>This field is only active when the ‘Age’ selected is Children or Both. Selecting ‘Yes’ triggers warnings to reconsent subjects at the age of majority.</td>
</tr>
<tr>
<td>Drug Accountability</td>
<td>Options are ‘Yes’, ‘No’, or ‘N/A’, and indicates whether drugs are being used and recorded within the protocol. This is an information-only field and is not used in any JeffTrial functionality.</td>
</tr>
<tr>
<td>*Investigator Initiated Protocol</td>
<td>Indicates whether the principal investigator initiated the protocol.</td>
</tr>
<tr>
<td>Involves Therapy</td>
<td>Options are ‘Yes’, ‘No’, or ‘N/A’.</td>
</tr>
<tr>
<td>Exclude Protocol On Web</td>
<td>Checking this box will exclude this protocol from displaying on the SIP (Study Information Portal).</td>
</tr>
<tr>
<td>Open For Affiliates Only</td>
<td>The Open for Affiliates Only field is used to indicate whether the protocol will only be opened for accrual at affiliate sites, not at the research center.</td>
</tr>
<tr>
<td>Summary Accrual Info. Only</td>
<td>When only high level (summary), subject data will be collected for a protocol, mark this field Yes. In this case, only a summary of subject accrual data will be collected on the Accrual tab in PC Console, and Subjects &gt; CRA Console &gt; New Subject Registration will be disabled.</td>
</tr>
<tr>
<td>*Protocol Type</td>
<td>Indicates the type of protocol and will be used for reporting purposes.</td>
</tr>
<tr>
<td>Registration Center</td>
<td>Typically used to indicate the type of organization responsible for subject registration. This is an information-only field and is not used in any JeffTrial functionality.</td>
</tr>
<tr>
<td>Involves Correlates or Companions</td>
<td>Marking this field ‘Yes’ enables the ‘Correlates &amp; Companions’ tab in the PC Console. This tab allows you to track correlates, in which you may track very basic specimen collection information or companion studies.</td>
</tr>
<tr>
<td>Data Monitoring</td>
<td>Records the party responsible for monitoring the protocol data. This is an information-only field and is not used in any JeffTrial functionality.</td>
</tr>
<tr>
<td>Adjuvant</td>
<td>Options are ‘Yes’, ‘No’, or ‘N/A’. This is an information-only field and is not used in any JeffTrial functionality.</td>
</tr>
<tr>
<td><strong>Includes Specimen Banking</strong></td>
<td>This function is not used at this time. Please leave this box unchecked.</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Companion Study</strong></td>
<td>Checking this checkbox indicates that the protocol is a Companion to another protocol. Marking a protocol as a companion study will allow you to add this as a companion to other protocols from the Correlates &amp; Companions tab on the corresponding protocol(s).</td>
</tr>
<tr>
<td><strong>Multi-site Trial</strong></td>
<td>Options are 'Yes' or 'No'</td>
</tr>
<tr>
<td><em>Investigational Drug</em></td>
<td>Options are 'Yes', 'No', or 'N/A'</td>
</tr>
<tr>
<td><em>Investigational Device</em></td>
<td>Options are 'Yes', 'No', or 'N/A'</td>
</tr>
<tr>
<td><em>Protocol Target Accrual</em></td>
<td>Use the Protocol Target Accrual to enter the number of subjects to accrue for the protocol, across all participating institutions (TJU and affiliates). The target accrual number entered displays in the top header of most pages. This DOES NOT refer to the national accrual goal.</td>
</tr>
<tr>
<td><strong>RC Total Accrual Goal (Lower)</strong></td>
<td>The Total Target Accrual (Lower) is the minimum side of the range for TJU’s total accrual.</td>
</tr>
<tr>
<td><em>RC Total Accrual Goal (Upper)</em></td>
<td>Total Accrual Goal (Upper) is the maximum side of the range for TJU’s total accrual.</td>
</tr>
<tr>
<td><strong>RC Annual Accrual Goal</strong></td>
<td>Indicate TJU’s accrual goal for the next calendar year.</td>
</tr>
<tr>
<td>Affiliate Accrual Goal</td>
<td>Affiliate Accrual Goal is the estimated number of subjects that will accrue at the Affiliate site participating on the protocol.</td>
</tr>
<tr>
<td><em>Accrual Duration (Months)</em></td>
<td>Accrual Duration (Months) estimates the number of months the protocol will be accepting subjects for accrual.</td>
</tr>
<tr>
<td>*Primary Completion Date</td>
<td><strong>Actual/Anticipated</strong> – The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. For active studies, select <strong>Anticipated</strong> and specify the expected completion date, updating the date as needed over the course of the study. Upon study completion, select <strong>Actual</strong> and update the date if necessary.</td>
</tr>
<tr>
<td>Study Completion Date</td>
<td><strong>Actual/Anticipated</strong> – Final date on which data was (or is expected to be) collected. Use the <strong>Anticipated</strong> or <strong>Actual</strong> choices as described above.</td>
</tr>
</tbody>
</table>
Management

In this horizontal tab, you can enter protocol management details. There are only 5 fields that must be completed: GCRC Participation, Automated Subject ID, Automated Sequence No., Internal Account No., and Management Group:

**Protocol → PC Console → Main (Vertical Tab) → Management (Horizontal Tab)**

*The IRB No. will be completed by the OHR staff when you receive an email from the portal confirming that your study has been accepted for a review.*

Refer to the following guide for completing GCRC Participation, Automated Subject ID, Automated Sequence No., and Internal Account No.:

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>*GCRC Participation</td>
<td>Indicates whether or not the General Clinic Research Center (GCRC) is providing support for the protocol</td>
</tr>
<tr>
<td>Automated Subject ID</td>
<td>JeffTrial provides the ability to automatically generate a subject ID. By selecting Yes in the Automated Subject ID field, JeffTrial will generate a unique ID for each subject registered to the protocol. This ID will be different from the MRN numbers used in electronic medical records and is simply a way for JeffTrial to keep track of subject count.</td>
</tr>
</tbody>
</table>
Automated Sequence No.  
JeffTrial provides the ability to automatically generate a sequence number for subjects. This is referring to the study ID a subject would receive when enrolled to a study. Please select No if you would like to designate the study ID on your own.

Internal Account No.  
If the study has an account number issued by Office of Research Administration (ORA#, 080#, or if departmentally funded, the department account #), enter it here. If the study has no external funding or if the account number is not yet available, leave the field blank for now.

Adding Management Groups to the Protocol

Next, you will need to select the appropriate Management Group for the protocol. Management Groups in JeffTrial are referring to the TJU departmental divisions (i.e. cardiology, pulmonary, etc.). To do this, hit the select button within the Administrative Groups section of the page:

Protocol → PC Console → Main (Vertical Tab) → Management (Horizontal Tab) → [Select]:

When you hit the [Select] button, a pop-up window (please deactivate your browser pop-up blocker) will come up and you can then select the appropriate management group(s) from the list by checking the appropriate select box and clicking on the [Add] button:

Management Group Browse Results:

If you do not see your specific management group, please contact the JeffTrial administrator.
Staff

The next horizontal tab is the Staff tab. Staff members are added at the protocol level here (This list will correspond to the OHR-1 key personnel list). Please keep in mind, the staff role (i.e. PI, Co-I, Protocol Coordinator) is not the same as the user role (i.e. ADMIN, PC, REG). The staff role grants them access to the protocol you have just created. To add staff members associated with the protocol, click on the Staff tab along the horizontal tabs:

Protocol → PC Console → Main (Vertical Tab) → Staff (Horizontal Tab):

Before entering any staff, you will notice that a Protocol Creator role has been created automatically. If you have additional roles within the study, add yourself again with the appropriate role designation.

To add additional staff, select the appropriate Role and type in the first or last name of the staff in the find-as-you-type field

- If the staff name does not appear in the list, please contact your local JeffTrial ADMIN first to add the staff into the system
- The start date does not have to be filled in immediately. It is recommended to be completed when the study delegation log is completed.
- Click [Add] to add the staff member to the protocol
- Following the initial study approval, the OHR staff will add any new personnel with an approved OHR-12B

If the protocol will utilize the same or a similar group of staff assigned to an existing protocol, JeffTrial provides the ability to select protocol staff by team. Click on [Select Team] to display a protocol selection field:

Protocol → PC Console → Main (Vertical Tab) → Staff (Horizontal Tab) → [Select Team]
When a protocol number is entered and the [Show Team] button is selected, a modal window will appear listing the protocol staff list. You may select the entire list to copy over to the new protocol by clicking [Select All] or individual staff can be selected by marking the ‘Select’ checkboxes.

- A staff member may be listed multiple times, with different roles on a protocol
- To edit a staff member’s Role, Institution, Start/Stop date or Stop Reason, click on the Edit hyperlink for the appropriate staff person. Institutions available for selection are those associated with the protocol. Changing a staff member’s Institution on this page applies only to this protocol; it does not affect the default institution listed in the Staff Record

**Sponsor**

The next horizontal tab is the Sponsor tab. Here, you can add the sponsor of the study. Simply click on the [Add Sponsor] button to the right side of the page to get started:

*Protocol → PC Console → Main (Vertical Tab) → Sponsor (Horizontal Tab)*

After clicking on the [Add Sponsor] button, a find-as-you-type field will appear where you can look for the correct sponsor(s) (If it is an internally funded study, please add either TJU or TJUH as sponsors):
Once you have selected a sponsor, you can click on the edit hyperlink to describe its role for the study:

The Sponsor’s protocol # is entered. The role in the study is selected and can be more than one.

If the sponsor you are looking for is not listed in the find-as-you-type field, then please complete a JeffTrial service request.

Lastly, additional study account numbers can be added within the Grant/Contract hyperlink on the right side of the page.

**IND/IDE Horizontal Tab**

The next horizontal tab is the IND/IDE tab. Here, you can answer whether the study involves an investigational drug and/or device:

- **Investigational Drug** – Yes or No
- **Investigational Device** – Yes or No

**Protocol → PC Console → Main (Vertical Tab) → IND/IDE (Horizontal Tab)**
If you select “Yes” to either question, you can enter additional information about the drug/device by clicking on the [Add] button:

Whether your study includes an investigational drug or device, the same 4 fields are required:

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>*ID</td>
<td>Enter the IND# (for investigational drug) or IDE# (for investigational device issued by the FDA)</td>
</tr>
<tr>
<td>Holder Type</td>
<td>The choices are Industry, Investigator, NCI, NIH, and Organization. Choose Industry if the sponsor holds the number. Choose Investigator if the local PI or a non-TJU individual holds it. Choose Organization if TJU or another non-corporate entity holds the number.</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Holder Name</td>
<td>Enter the name of the individual, sponsor, or other entity that holds the IND or IDE number.</td>
</tr>
<tr>
<td>Comments</td>
<td>In this field, type in the full name of the investigational drug or device.</td>
</tr>
</tbody>
</table>

Please make sure to click on the Save hyperlink to the right of the page to save any information.
Treatment (Vertical Tab)

The next vertical tab is called Treatment. In this tab, you can add study arms and study drug/device information to JeffTrial. This is a very important and necessary step to properly prepare the protocol for calendar creation.

To get started with this tab, add a step code (i.e. 1, 2, 3...), select Registration or Randomization, and click on the [Add] button:

*Protocol → PC Console → Treatment (Vertical Tab) → Details (Horizontal Tab)*

Adding Arms to the Study

Once you have added a protocol step, an Arms hyperlink will appear as shown above. By clicking on the hyperlink, you will be able to add as many protocol arms as necessary.

To enter a protocol arm, add an arm code (i.e. A, B, C...), type in a brief description of the treatment group, and click on the [Add] button.
If the protocol has multiple arms, please enter all applicable arms in this page as it is necessary for creating a protocol calendar properly.

Once you have added a protocol arm, a Modalities/Drugs/Devices hyperlink will appear as shown above. By clicking on the hyperlink, you will be able to add a modality, study drug, or device to the corresponding arm:

Modalities/Drugs/Devices
To enter a modality, study drug, or device, simply search for the modality/drug/device in the appropriate find-as-you-type field and click on the [Add Modality] / [Add Drug] / [Add Device] button.

Please remember to only add the appropriate modality/drug/device to the selected arm. To add a modality/drug/device to another arm, click on the [Close] button to go back and [Add] another arm.

If the modality, drug, or device you are looking for is not in the list, please complete a JeffTrial service request.
**Institution (Vertical Tab)**

The next vertical tab is called Institution. In this tab, you can add any participating institution(s) to the protocol.

To get started, click on the add button:

*Protocol → PC Console → Institution (Vertical Tab)*

![Image of Institution tab](image)

To add an institution, please follow this guide:

1. Click on the search button located below the institution field. This will bring up a pop-up window (*disable pop-up blocker*) with a list of institution hyperlinks to choose from.
2. If adding Thomas Jefferson University, then simply click on the hyperlink and then click on save. If adding any other institution, check off whether or not the other institution uses the research center IRB (TJU IRB).
3. Click [Save] for each institution you choose.
**Protocol Institution**

To view institution specific information, you can click on the added institution's hyperlink. This will bring up the Protocol Institution page:

The following vertical tabs are available within the Protocol Institution page:

<table>
<thead>
<tr>
<th>Tab</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff</td>
<td>You can view/add/edit institution staff members and enter any regulatory information to an individual (i.e. 1572, financial disclosure, investigator agreement). Any CV's and licenses, along with their expiration dates attached to a staff member will also appear on this page</td>
</tr>
<tr>
<td>Regulatory Items</td>
<td>You can view/add any lab or IRB regulatory items for the institution on this page (i.e. CLIA, CAP, IRB roster)</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>IRB Reviews</td>
<td>You can view/add/edit institution specific IRB review information</td>
</tr>
<tr>
<td>Consent Forms</td>
<td>View and download approved consent forms</td>
</tr>
<tr>
<td>Checklists</td>
<td>Update any protocol institution-specific checklists</td>
</tr>
<tr>
<td>Study Sites</td>
<td>View study site accrual information</td>
</tr>
</tbody>
</table>

This concludes the protocol creation portion of the training. Now you are ready learn about the calendar validation process of protocol management.
PART II: Calendar Validation

Once the protocol has been successfully created, if the protocol is in need of a protocol calendar, a calendar will be created. In this section, you will learn how to successfully validate a protocol calendar.

Calendars/Specifications

Protocol calendars describe a study’s visits and the procedures and treatments to be administered at each of those visits. In JeffTrial, calendars also include the MCA billing designations as well as tie into study invoicing procedures. It is a tool that ties in many of the different areas involved in a clinical trial together.

Once a calendar is completed and released, it will be used by study coordinators to manage all aspects of subject participation in the study: planning visits, confirming their occurrence, and recording clinical data generated during a visit.

However before a protocol calendar can be used, it must be validated by the appropriate investigator/coordinator to ensure that all of the details of a calendar are accurate and meets the needs of the research personnel.

In JeffTrial, calendars that are in progress (still being created / going through validation process) are referred to as “Specifications”. These specifications can be found within the eCRFs/Calendars menu as seen below:

![eCRFs/Calendars ➔ Specifications](image)

Protocol Specifications

After clicking on the Specifications page, you will be able to locate your designated protocol specifications in the “Protocol Specifications” tab as shown below:

![Protocol Specifications](image)

Please note, you must be listed on the protocol staff section of the PC console to be able to access the appropriate specification.
**Study Specific Validation**

Once again, calendars in JeffTrial must be validated by the appropriate research personnel to ensure accuracy before being released for use.

To access these calendars for validation, simply click on the protocol number hyperlink on the left hand side of the Study Specification page to view:

*eCRFs/Calendars ➔ Specifications ➔ Protocol Specifications*

---

**Treatment Visits**

Treatment visits will be the first page of a protocol specification. This page will list out all of the treatment visits that will occur in a given protocol:

*eCRFs/Calendars ➔ Specifications ➔ Protocol Specifications ➔ Treatment Visits:

This is the first step in validating a protocol calendar. This page will list out the treatment visits for the calendar. Please review carefully to make sure that visits are accounted for (though it’s easier to review this on the next page) and more importantly, that the visits have a correct corresponding “start date” (i.e. Consent Signed, On Study, On Arm, On Treatment, Off Treatment...Off Study).

This page may be a bit confusing for a study coordinator as it includes fields used by the calendar builder to create the intricacies of a calendar in the background. However, before simply moving onto the next page, a coordinator should review this page just to see how a calendar is built from the ground up.
Calendar

The Calendar page is where you can really get into the validation process as it includes the calendar grid that is written out in the original protocol:

**eCRFs/Calendars → Specifications → Protocol Specifications → Calendar:**

The main feature of the calendar page will be the calendar grid that includes three different aspects of a typical protocol calendar: treatment visits, procedures, and procedure schedule.

The treatment visits that were entered in the previous page will be located on the top of the grid, replicating what is on the original protocol. When you are validating your calendars, you should first make sure that all of the treatment visits are accounted for and labeled correctly.

Next, all of the protocol procedures will be listed on the left hand side of the grid, exactly as it is written in the original protocol. This should be verified as well to ensure that no procedures have been left out. In addition to this, the procedures will be assigned to the appropriate treatment visits according to the original protocol.

If a protocol has any footnotes, they will be typed out below the grid towards the bottom of the page. The footnotes will not serve any operational purposes when using calendars, but do provide important reminders for coordinators when completing a visit.

Lastly, a JeffTrial calendar also comes with visit windows to ensure that any visits occurring outside of a specific window are flagged. The visit windows can be validated by clicking on any of the treatment visit hyperlinks to check what has been entered:
The tolerance number can be set to any whole number. JeffTrial calendars use years, months, weeks, and days as units of choice. Unfortunately at this time, it does not use hours or minutes as units. And since the tolerances only use whole numbers, nothing can be set to less than one day.
**Preview Calendar**

The last part of a calendar validation is making sure that each of the treatment visits occurs as they should. To do this, you can click on the “Preview Calendar” button towards the top right side of the page:

**eCRFs/Calendars → Specifications → Protocol Specifications → Calendar (Preview Calendar):**

After clicking on the preview calendar button, a small window will pop up that includes a number of parameters for the coordinator to enter.

**Preview Calendar Parameters:**

The parameters can range from “Consent Signed Date” to “Off Study Date” and anything in between (i.e. “On Study Date”, “On Treatment Date”, etc.). You can enter hypothetical dates for any of these parameters and click on Preview to “test” out if the rest of the calendar will occur as they should.

After clicking on the preview button, the calendar grid will then include a row of calculated dates for each of the treatment visits based on the hypothetical test dates that you entered.
Calendar Validation Queries or Completion

If you come across any issues while going through the validation process, you will need to contact the calendar builder to let them know that there is an issue with any or all parts of the calendar.

The best most efficient way to do this is download the protocol grid in an excel format as shown below:

\[eC\text{R}Fs/C\text{a}\text{le}\text{nd}\text{ars} \rightarrow \text{Specifications} \rightarrow \text{Protocol Specifications} \rightarrow \text{Calendar (View Excel):}\]

![Calendar Grid](image)

Within the downloaded excel sheet, any changes (removal of procedure/treatment visit, addition of procedure/treatment visit, wording correction, etc.) should be done with a different colored text so that the calendar builder can easily distinguish it from the original.

Once any and all changes have been made to the excel spreadsheet, attach it to an email with any additional comments (if necessary) and send it to the calendar builders.

This concludes the calendar validation portion of the training. Now you are ready learn about the JeffTrial IRB submission process of protocol management.
PART III: IRB Submission & Checklist Maintenance

In this section, you will learn how to submit the protocol to the IRB and about checklist maintenance.

New IRB Submissions

New IRB submissions require the use of both JeffTrial and the IRB Portal. Initially, you will enter the necessary information within the JeffTrial IRB submission tool and then use the IRB Portal to upload the necessary documentation. Submissions will NOT be reviewed unless the appropriate information is entered into JeffTrial.

*Please note, when submitting a study to the portal, be sure to include the JeffTrial Protocol number (the auto-generated number) so that the OHR staff can match the reviews.

To start this process in JeffTrial, open the IRB horizontal tab within the Reviews tab of the PC Console and click [Add]:

Protocol → PC Console → Reviews (Vertical Tab) → IRB (Horizontal Tab) → [Add]
In the Review Information section shown above, you are only responsible for entering the Submit Date and the Review Reason. The Submit Date will indicate on what date the protocol is submitted to the IRB via the Portal and/or paper copy. The Review Reason is the type of IRB submission. For a new study submission, choose Initial Review. When complete, click on the [Create] button at the bottom of the page.

In the Details section, you are also required to LIST all of the documents being submitted to the portal. To do this, click on the [Add] button for EACH of the documents being submitted, and complete the following:

1. Type – You must choose all of the documents being submitted to the IRB and a separate type labeled, “IRB Submission Package”
   a. You are not required to complete any of the other fields for “IRB Submission Package”
2. Amendment Number (if applicable)
3. Version Date (Date Based on the Footer of the ICF)
4. Description (i.e. Name of Document - Short Title - mm.dd.yyyy)
a. Completing the description field is important because it appears in the Institution tab’s consent page.

5. Check Global IF the same consent will be used at affiliate sites

6. Click on the Save hyperlink on the right

**OHR Staff’s Responsibilities**

The following is a quick overview of what the OHR will be responsible for within the JeffTrial new submissions process:

- The OHR staff will complete the IRB reviews page within 5 business days of the committee decision. If the decision is conditional, they will enter the appropriate fields following the latest updated document.

- The fields that will be completed are as follows:
  - Review Date, Committee, Review Type, Action, Action Date, Expiration Date, and Received Date
  - The received date corresponds to the date the OHR accepts the package submitted through the IRB portal for review

**Fields to be completed by the OHR Staff**
**IRB Approval Received**

After you have received the IRB approval for your study, you can choose to upload all approved documents into JeffChart for further use.

To do this, you must re-enter the IRB page within the Reviews vertical tab and open up the IRB transaction by clicking on the **Edit** hyperlink (Make sure it is for the Initial Review transaction):

**Protocol → PC Console → Reviews (Vertical Tab) → IRB (Horizontal Tab)**

To upload a specific document, in the following page, locate the document type in the Details section near the bottom of the page and look for the **File** hyperlink:

- Clicking on the **File** hyperlink on the left allows you to attach the appropriate document
• Select the proper document (scanned PDF of IRB approved documents) and then click on the [Submit] button to save and complete your IRB submission.

• Finally, check off the Release box and [Submit] to view the documents in other sections of JeffTrial:
  o Releasing a document will allow users with access to this study to view and download the documents in the Documents/Info tab.
  o A released Consent can only be viewed/downloaded through Document Search or in the Protocol Institution Tab (see Part I).

The information you have added becomes part of the history for this study submission. Various reports can be generated based on the data in this field.

**Amendment & Renewal Submissions**

The process of submitting an amendment or a renewal to the IRB is similar to submitting the initial submission, but with a few key differences:

1. Renewals will be identical to submitting an initial review with the only difference being the “Review Reason”

2. When you need to submit an amendment, prepare your OHR documents as normal, however DO NOT make any data changes in JeffTrial yourself.

3. If the amendment requires the addition of a new staff, you must contact the JeffTrial ADMIN to ensure that the staff is added into the system first.

4. If the amendment requires the addition of a new sponsor, drug, and/or device, you must complete a JeffTrial service request PRIOR to submitting the amendment to ensure that any addition is added into the system first.
   a. All other amendments can be submitted without completing a JeffTrial service request.

5. Afterward, complete the amendment submission process through the Portal and JeffTrial as described on page 30-31 of this training document.

6. Following the approval, the necessary JeffTrial changes will be made by the OHR staff.
7. As was done before in the initial submission, you must upload all approved documents (scanned PDFs) into JeffTrial.

8. It is also recommended that you review the changes made to ensure accuracy of data. If the data is incorrect, please contact Jennifer Polizzi of the OHR at Jennifer.Polizzi@jefferson.edu

Documents/Info

In this tab, you can upload protocol related documents that DO NOT need IRB approval, including but not limited to sponsor protocols, investigator’s agreement, 1572, and financial disclosures:

Protocol → PC Console → Documents/Info (Vertical Tab) → Attachments (Horizontal Tab)

To add a document, click on the [Add] button as shown above. This will bring up additional fields for you to complete:

- Document Type
- Attach a file by clicking on the File hyperlink
- Version Date
- Description (i.e. Name of Document - Short Title - mm.dd.yyyy)
- Click on the Save hyperlink on the right
Metric Collection via the IRB Checklist

Users of JeffTrial can utilize the checklist function to track protocol related tasks or activities for metric collection purposes. Various checklists are located in the Status tab of the PC Console:

*Protocol → PC Console → Status (Vertical Tab) → Checklist (Horizontal Tab)*

The checklist items are customizable. If you would like to make any new additions, please complete a JeffTrial service request.

When you receive new IRB metrics, open up the IRB checklist by clicking on the checklists button to the right and subsequently, clicking on the IRB vertical tab on the left hand side of the page.
To update any of the checklist items, simply click on the appropriate hyperlink to bring up the Checklist Item Communications page, where you fill in the date and any comments if necessary:

**Checklist Item Communications**

This concludes the IRB submission part of the coordinator training. Next you will learn about opening the study for enrollment and subject registration.
PART IV: Opening the Study & Subject Registration

In this section, you will learn how to open the study for accrual and how to register a subject.

Opening the Study

Once the study's contract is executed, you are ready to open the protocol to accrual in JeffTrial. To do so, you will need to go to the Status vertical tab of the PC Console:

Prototype → PC Console → Status (Vertical Tab) → Status (Horizontal Tab)

Assuming that at this point, the IRB has approved your study, you will see two changes to this page. First, you can see that the Protocol Status in the header has changed from NEW to IRB INITIAL APPROVAL. Second, you can find an [Open] button near the bottom right side of the page. Click on this button, enter the Status Date, and click on [Submit]:

After clicking on the [Submit] button, you will notice that the Protocol Status changes to OPEN TO ACCRUAL. And now, you are ready to enter new subjects into JeffTrial for accrual.
Entering New Subjects

New study subjects are entered in the CRA Console. The CRA Console can be found under “Subjects”, located in the menu bar. You can also manage your accrued subjects in this console, if they have been entered. To change the view of this page (i.e., to see All subjects, Eligible subjects, etc.), select from the drop down box on the right. Additionally, you have the option of sorting all accrued subjects by the various column headings (Last Name, MRN, Sequence Number, etc.). You may select Save Preferences on the bottom right hand side in order to see this same view every time you log in. Below is an example of what the CRA Console looks like with previously entered subjects:

Subject ➔ CRA Console, Select Protocol:

To enter a new study subject, first select the correct protocol in the find-as-you-type field and then click on the New Subject Registration vertical tab:

Subject ➔ CRA Console, Select Protocol, New Subject Registration (Vertical Tab):
New Subject

Subject \(\rightarrow\) CRA Console, Select Protocol, New Subject Registration (Vertical Tab):

When entering a new study subject, first select the Study Site from the top find-as-you-type field. Second, to prevent duplicate subject entry, search for your subject in the Find Fields section.

If the subject is an existing patient in JeffTrial, you can click on their Subject ID at the bottom of the page. This will automatically fill in the subject details for you to verify. Click [Add] if it is the correct subject.

If the patient is not already in the JeffTrial system, then fill in the required fields on this page:

- Subject ID (PLEASE CLICK ON THE [Generate] BUTTON) – This refers to the JeffTrial subject ID number. It is used to make sure there are no duplicate subjects within the system. This is NOT an inpatient/outpatient MRN.
- Last Name
- First Name
- Birth Date
- Gender
- Ethnicity
- Race
- [Add]

This will take you to the demographics page of the subject console. From here, the study coordinator will continue to fill in the necessary information to add the subject to the protocol.
Demographics

You are now in the Subject Console of JeffTrial. This is where you can view/edit individual subject information based on the selected protocol. Just like in the PC Console, the process will be to follow the vertical tabs from top to bottom. As you move from one vertical tab to another, you will notice a change in the Subject Status at the top right side of the page.

Subject → Subject Console, Demographics (Vertical Tab):

In the Demographics page, you can enter any additional demographic information, including the subject MRN number(s) and their contact information.

For MRN, select the Identifier Type (JeffChart/AllScript) and the appropriate Identifier (MRN number), and click the Add hyperlink (Identifier Owner is not needed).

There is no additional required information to be entered on this page. However, you may choose to enter as much information as you would like.

After you click on the [Submit] button at the bottom of the page, continue to the next vertical tab, in this case, Consent.
Consent

*Pleased note, you will only be able to continue IF the proper consent document has been listed and subsequently approved by the IRB.

The first step in enrolling a subject to the study is consenting. In the Consent page, click on the [Select Consents] button in the middle of the page to open up the available consents page:

Subject → Subject Console, Consent (Vertical Tab):

Once opened, complete the Signed Date and Status fields for the appropriate consent and click on the [Save] button at the bottom of the page.

You may use the section below to add any comments if necessary. If comments have been added, be sure to click on the [Submit] button before moving on to the next vertical tab.

If you enter the proper information on this page, you will see that the Subject Status now shows CONSENTED.
Eligibility

After consenting the subject, you must complete their eligibility status. Below is a screenshot of what the Eligibility tab looks like:

Subject ➔ Subject Console, Eligibility (Vertical Tab):

At this time, you are only required to complete the Eligibility Status and the Status Date fields. For some protocols, the status date for eligibility may be the same as consent date.

If the subject is not eligible or withdraws, please complete the appropriate fields on this page.
On Study

In this page, you will officially add the subject to the study by declaring the ‘On Study Date’. For our purposes, there are four fields on this page that we will focus on: Sequence No., On Study Date, Study Site, and Subject Staff:

Subject → Subject Console, On Study (Vertical Tab):

The Sequence No. refers to the number that the subject receives when enrolled (i.e. 111-001). If you selected “Yes” to the “Automatic Sequence No.” field back in PC Console → Management, this number will be auto-generated beginning with 1 when you complete the “On Study Date” field. If you selected “No”, then you can enter your own sequence number for the subject.

If there are multiple sites that will be enrolling subjects for this study, be sure to select the appropriate study site for this subject.

You can also add the subject staff for the subject (Note, this is different from adding staff to the protocol). By adding the staff in this section, it grants those staff access of seeing this subject in their My Console (found in the Menu Bar, will be further detailed later in the manual). It is recommended that you add the primary study coordinator, the backup study coordinator, and the principal investigator. Once again, like with other staff sections, you can choose to add the staff one by one, or add multiple staff by clicking on the [Team] button.
**Treatment**

*Pleased note, you will only be able to add an ARM on this page IF the proper arm(s) has been added.*

In this page, you can add the subject to a specific arm if there are multiple arms, an On Arm Date, On Treatment Date, and Off Arm Date. To do so, first click on the [Add] button to reveal the additional fields:

**Subject ➔ Subject Console, Treatment (Vertical Tab):**

When the additional fields appear, select the appropriate arm for the subject and fill in the corresponding dates. Finally, be sure to click on the **Save** hyperlink on the right side to save the changes.
**Follow-Up**

In this page, you can add the Off Treatment Date (reason), Off Study Date (reason), Follow-Up Date (if appropriate), and any other pertinent information:

**Subject ➔ Subject Console, Follow-Up (Vertical Tab):**

*Please note, typically, after adding the subject to an arm, you will jump to the calendar portion of the system to continue with the visit check in process (see Part II of this training manual).*

If you would like to add a specific Off Treatment/Off Study reason, please complete a JeffTrial service request.

This concludes the subject registration training. Please continue to the next part of the training, Patient Calendar and My Console.
PART V: Subject Calendar and My Console

In this section, you will learn about using the subject calendar to complete a subject visit and to track visits using both the calendar and the My Console of JeffTrial.

Subject Calendar

After you have added the subject to an appropriate arm, the next step will be to move on to the subject calendar section:

Subject ➔ Subject Console, Calendar (Vertical Tab):

These calendars should mimic the calendar grid that exists in the study protocol with the appropriate procedures, treatment visits, and when they should occur. Therefore, the first thing to do following the completion of subject registration will be to complete the first treatment visit. To do so, please click on the very first hyperlink on the calendar grid (typically the Screening visit).
Clicking on the hyperlink will open the appropriate subject visit update page. Here, you can indicate when the visit date was, whether the visit occurred/missed/NA, and if necessary, indicate if certain procedures were missed:

**Subject Visit Update:**

It is imperative that if a procedure was missed, that it is marked as missed so that the billing team does not invoice for a procedure that did not take place.

After completing the necessary fields and clicking on the [Submit] button, you will see a few additional buttons appear at the bottom of the page, [Additional Procedures], [Billing Slip], and [View PDF]. The latter two of those three allows you to see the visit summary in a more condensed format. The [Additional Procedures] button allows you to attach any additional, unscheduled procedures that may have taken place during the visit:
Subject Visit Update (Additional Procedures):

As with the potential missed procedures, it is important to make sure that any additional procedures are accounted for so that the billing team can invoice for everything that took place during a subject visit.

Each visit in the calendar should be calculated out based on the protocol’s specifications. Therefore, users should repeat this process with all of the other visits listed in the subject calendar at the appropriate times. The visits will also include (if applicable) visit windows. So if a visit does happen to occur outside of the window, the system will notify you of this and you will be able to indicate why the visit occurred out of window.

Completing these visits in a timely manner will also ensure that the grants administrators will be up-to-date with subject visit completions for invoicing purposes.
Additional (Unscheduled) Visits

Users also have the ability to record any additional (unscheduled) visits into the system. To do so, you can simply click on the Additional Visits vertical tab to open up this page:

By clicking on the [New] button, you will open up a Subject Visit Update page similar to the regularly scheduled visits. On this page, complete the Visit Date field and click on the [Submit] button to bring up the [Additional Procedures] button as shown above. And then you can add any appropriate procedures that took place during the unscheduled visit.
**My Console**

My Console is designed specifically to assist staff in managing subject visits across all of the staff’s protocols. It provides a means to view and verify visits without having to access each subject individually from the CRA Console and Subject Console.

My Console can be found under “My Console”, located in the menu bar:

![My Console](image)

The initial My Console page will take you directly to the Protocol menu vertical tab where all protocols to which you are currently assigned will be viewable. Additional tab choices are Subjects, Subject Visits, and My Calendar.

**Protocols**

First, in order for a protocol to be listed in My Console, you must be listed as a current Protocol Staff, regardless of the role.

A protocol must also have an active status of Open to Accrual or Closed to Accrual to appear in My Console. Protocols that have a NEW, IRB Initial Approval, or IRB Study Closure will not display in the Protocol list:

**My Console → Protocols**

![Protocols Table](image)

From the Protocols tab in My Console, you can jump to any of the protocols listed by clicking on the Protocol No. hyperlink. You will be redirected to the PC Console where protocol information can be updated, as long as you have the appropriate permissions.
Subjects

As with protocols, only subjects where you are assigned as a current Subject Staff, regardless of role, will appear in My Console.

My Console ➔ Subjects

Initially, active subjects on active protocols are shown, but this can be changed using the filter controls in the upper right of the page. Unchecking the ‘Show Active Protocols Only’ checkbox will cause subjects from all of your currently assigned protocols to display.

Selecting a different Subject Status from the dropdown will cause subjects of different statuses to display. The available choices and their corresponding Subject Statuses are:

- On Follow-Up: “Off Treatment”, “On Follow-Up”
- All

The default sort order is by Protocol No. (first by number then alphabetical) and then Last Name, Initials, or none depending on your assigned subject identification privileges. Clicking on a column header causes the table to be sorted by that column. A secondary sort can be applied to the table by right-clicking on the header and selecting a secondary sort column from the list. Once you select a column or columns for sorting, that sort preference will remain intact for you on this page until you select a new sort order. This remains true even after you log out of the application and later log back in.

Subject Visits – Occurred

Subject visits that have occurred can be viewed in a list format on this page. It will include various information about each of the visits including the protocol number, subject name and sequence number, and visit description and date.

Subject Visits – Pending

Likewise, pending subject visits can also be viewed in a list format in the “Pending Visits” tab. This page will include everything seen on the occurred visits page plus when the visit is planned, visit window (if applicable), and even the ability to enter the actual visit date.
My Calendar

The My Calendar vertical tab displays a monthly, weekly or daily calendar with the visits of your currently assigned subjects and/or all subjects in your currently assigned protocols. You will also see the subject sequence number in parenthesis after subject name/subject initials depending on your privileges. If there is no sequence number assigned to the protocol subject, the parenthesis will not be seen. By default, the monthly view will display both your currently assigned subjects and subjects from your currently assigned protocols:

My Console → My Calendar (Month View)

You can change your Calendar view options by clicking the appropriate icon under the My Calendar title. The leftmost Icon will display a daily view, the second icon displays a weekly view, the third icon displays a monthly view, and the rightmost icon returns the display to the current month/week/day, depending on your current view.

Checking the ‘Include Subjects From Assigned Protocols’ checkbox will display Subjects from Protocols where you are currently assigned as a Protocol Staff. Checking the ‘Include Assigned Subjects’ checkbox will display subjects that you are currently assigned to as Subject Staff.

At the bottom of the page, the [Print] button exports the My Calendar data to a PDF format.

This concludes the subject calendar portion of the training.
PART VI: Protocol Search

In this section, you will learn about the protocol search function of JeffTrial.

The Protocol Search section of JeffTrial allows you to find a specific protocol or protocols based upon a variety of criteria. Report results can be exported to PDF or Excel formats.

The Protocol Search page is accessed by the **Protocols ➔ Protocol Search** menu item. The page provides multiple fields for entering search criteria. Several fields are labeled Multi-Select, allowing more than one value to be considered a ‘match’ when conducting a search.

The search criteria fields are arranged into sections. To aid visibility, some section headings include [+] and [-] hyperlinks to display and undisplay the section’s fields.

You may use any number of fields from any combination of sections to define the criteria for your protocol search. After entering your criteria, click the **Search** button to generate a list of matching protocols.

Search criteria may be removed from all fields by clicking the Clear button.
Protocol Search Options

*Filter Type*

Filter Type radio buttons are available throughout the Protocol Search page and may be used to refine your search criteria:

To include protocols that have *any* of the selected criteria, select the ‘Contains Any (OR)’ radio button. To include protocols that meet *all* of the criteria listed, select the ‘Contains All (AND)’ radio button. To *exclude* protocols that meet the selected criteria, select the ‘Does Not Contain’ radio button.

*Sort By (Initial Sort)*

At the bottom of the Protocol Search page are two fields used to determine the initial order of the search results. Results may be sorted by one of a number of fields, in Ascending or Descending order.

Initially, you are provided this default sort order:

Use the fields to select different criteria:

These fields determine the sorting criteria used when the search results page is initially displayed. The search results page has its own sorting.

*Search Results*

Search results vary depending upon inclusion criteria. The following screenshot is an example of Protocol Search results:
The header displays the search criteria used. Column headers are hyperlinks. Clicking a column header hyperlink will sort the results based on the data in that column (by default, sorting is alpha/numeric based). A subsequent click on the column header hyperlink will sort in 'reverse' order.

In the body of the report, each row represents one protocol. Protocol numbers are usually displayed as hyperlinks. Selecting a hyperlink brings you to the PC Console → Main → Details tab for that protocol. If no hyperlink is available, you do not have the privileges required to view the protocol.

You may change the number of results available by selecting a different value from the Page Size drop-down menu. An additional filter may be applied to reduce the results by typing any filter criteria. Finally, the results page number may be selected or you may scroll through the pages by clicking the arrows available to you.

The bottom section of the result page displays the number of protocols matching the search criteria, and buttons to view or export the data in different formats.

Clicking on the [Back to Search] button takes you back to the search page where you may modify your search. Clicking on the [View Excel] button will
transfer the results to an Excel spreadsheet. Clicking on the [View PDF] button will create a PDF version of the results.

**Configuring Search Result Display**

By default, the results display the following fields: Protocol No., Additional Protocol Numbers, Department, Title, current PI Name (according to Protocol Staff Start Date/Stop Date information), Current Status, Status Date, and Priority Score. By checking the checkbox to the left of a search field, the data for that field will be included in the results. The field does not need to be used as part of the search criteria.

Checkboxes that are checked and disabled are required for the output and will always be shown. Checkboxes that are checked on the main Protocol Search page can be cleared by clicking the [Clear] button.

**Protocol Search Criteria Fields**

Protocols are found based upon the search criteria entered into the Protocol Search fields. The following sections explain how these fields are used.

Remember - multiple fields can be selected for an individual search. Selecting multiple fields will narrow the search results; all of the search criteria need to be met before the protocol will be selected for the result list.

**Protocol Status**

You may select any number of protocol statuses to search on for a date range.

Searching on status requires you to enter information in the From Date and Thru Date fields. Using these fields narrows your search and will retrieve protocols assigned to the specified status(es) at any point during the date range.

For example, if a protocol is new or received IRB Initial Approval at any time in 2013, it will be found by the criteria specified in the screenshot above.

Searching based on Status Change will show any protocols that were changed to that status during the date range.
Using the example in the screenshot above, if a protocol was opened to accrual at any time in 2013 it would display in the result list.

The Pending/Active/Completed checkboxes at the bottom of the Protocol Status section applies to the main protocol status. The Pending checkbox will select protocols not yet Open to Accrual. The Active checkbox will select protocols with a status of Open, Closed, or Suspended. The Completed checkbox will select protocols that have a status of Abandoned, Terminated, or IRB Study Closure.

**Participating Institution**

The Participating Institution section gives the ability to find protocols where the specified institution has been added on the PC Console > Institution tab and has a status of Pending, Active, and/or Completed. The Institution and Pending, Active, and Completed checkbox fields work in conjunction with each other.

Selecting an institution requires you to select a Pending/Active/Complete status and *vice versa*. (The Research Center institution is not available in this Institution field. To searching on the Research Center’s status, see the previous Protocol Status section.)

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol No.</td>
<td>This is a flexible search field. If you enter 'BMT' in this field, a list of all protocols containing 'BMT' in their protocol number will display. All of a protocol's numbers are considered, including the IRB Number, Pharmacy Number, and Sponsor Number.</td>
</tr>
<tr>
<td>Summary Accrual Only</td>
<td>By marking this checkbox the results will be limited to protocols where the Summary Accrual Info Only has been set to Yes on the PC Console ➔ Main ➔ Details tab.</td>
</tr>
</tbody>
</table>
Open For

This drop-down field is used to search for 'All' protocols (default), protocols open at RC/CC **not** marked as 'Open for Affiliates Only' on the PC Console → Main → Details tab, or protocols that are open for affiliates only **marked** as 'Open for Affiliates Only' on the PC Console → Main → Details tab. This search criterion does not look at the protocol status.

Title

This field looks for matches in either the title or the short title entered for each protocol on the PC Console > Main > Details tab. An entry in this field will be used for full or partial matching. For example, searching for parts of the whole title such as 'meta' or 'static' will return protocols with 'Metastatic' in the title.

Institution

This search will show protocols with the institution(s) assigned on the PC Console → Institution tab. This search criterion does not look at the institution status.

**Protocol and Participating Institution Status Searches**

When you want to search on the Research Center’s protocol status and the status of a participating institution at the same time, both of the previous sections need to be used.

**Staff**

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff Name</td>
<td>This field will select protocols with the staff member assigned as Protocol Staff or Subject Staff, based on the Scope field setting outlined below. (This and other Staff fields do not take into account the Start Date or Stop Date information of the staff on the protocol or subject.)</td>
</tr>
<tr>
<td>Staff Role</td>
<td>Selecting a Staff Role will limit the results to protocols having Protocol Staff or Subject Staff assigned to the role. A column in the results will display all staff members assigned to that role.</td>
</tr>
<tr>
<td>Scope</td>
<td>The Scope drop-down field can be used to determine whether the search using the Staff Name and Staff Role should look for the staff as Protocol Staff only, Subject Staff only, or both. When the field is blank JeffTrial searches both Protocol Staff and Subject Staff.</td>
</tr>
</tbody>
</table>
Main

The search fields contained in the Main section refer to data stored on the PC Console → Main → Details tab.

<table>
<thead>
<tr>
<th>Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Group</td>
</tr>
<tr>
<td>Data Monitoring</td>
</tr>
<tr>
<td>Department</td>
</tr>
<tr>
<td>Investigational Drug</td>
</tr>
<tr>
<td>Investigator Initiated Protocol</td>
</tr>
<tr>
<td>Phase</td>
</tr>
<tr>
<td>Scope</td>
</tr>
<tr>
<td>Protocol Type</td>
</tr>
<tr>
<td>Summary 4 Report Type</td>
</tr>
</tbody>
</table>
Management

The search fields contained in the Management section correspond to the PC Console → Main → Management, Sponsor, and IND/IDE tabs as well as the Institution tab.

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GCRC No.</td>
<td>NCI Trial ID</td>
</tr>
<tr>
<td>Hospital Account</td>
<td>PRMC No.</td>
</tr>
<tr>
<td>Internal Account No.</td>
<td>Toxicity Scheme</td>
</tr>
<tr>
<td>IRB No.</td>
<td>Program Area</td>
</tr>
<tr>
<td>Management Group</td>
<td>Sponsor Type</td>
</tr>
<tr>
<td>NCT Id.</td>
<td>Sponsor Role</td>
</tr>
<tr>
<td>Network</td>
<td>Principal Sponsor Only? Checkbox</td>
</tr>
<tr>
<td>Oncology Group</td>
<td>IND ID</td>
</tr>
<tr>
<td>PDQ No.</td>
<td>IDE ID</td>
</tr>
</tbody>
</table>
**Treatment**

The search fields contained in the Treatment section correspond to the PC Console → Treatment → Details and Disease/Diagnosis tabs.

![Treatment search fields](image1.png)

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease Site, Diagnosis Group</td>
<td></td>
</tr>
<tr>
<td>Drug</td>
<td></td>
</tr>
<tr>
<td>Modality</td>
<td></td>
</tr>
</tbody>
</table>

**Accrual**

The search fields contained in the Accrual section correspond to the PC Console → Main → Details tab and actual accruals associated with a protocol.

![Accrual search fields](image2.png)

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AF Accrual</td>
<td>By selecting the checkbox for AF Accrual, the search results will include a column indicating the actual Affiliate accrual for the protocol.</td>
</tr>
<tr>
<td>RC Accrual</td>
<td>By selecting the checkbox for RC Accrual, the search results will include a column indicating the actual Research Center accrual for the protocol.</td>
</tr>
<tr>
<td>VA Accrual</td>
<td>By selecting the checkbox for VA Accrual, the search results will include a column indicating the actual accrual for the institution type of 'VA' (Veteran's Administration) for the protocol.</td>
</tr>
<tr>
<td>Total Accrual</td>
<td>By selecting the checkbox for Total Accrual, the search results will include a column indicating the actual total accrual for the protocol.</td>
</tr>
<tr>
<td>Target Accrual</td>
<td>By selecting the checkbox for Target Accrual, the search results will include a column indicating the Protocol Target Accrual listed on the PC Console → Main → Details tab, Accrual Information section.</td>
</tr>
<tr>
<td>Accrual Reporting Period</td>
<td>When the date range fields in this frame are used, the Accrual displayed using the columns described above will show the accrual for the date range entered. The columns will display the total accrual if the date range is not entered.</td>
</tr>
</tbody>
</table>
Saved Protocol Searches

Search criteria that are used often may be saved to increase your searching productivity in the future.

After you have created a Protocol Search that you would like to be able to run again, you can save it by clicking the [Save As] button near the top of the page. A prompt box will pop up where you can enter a name for the search and then click the [Save] button.

To recall a saved Protocol Search, select it in the Saved Searches field. The search name will display, and the saved search criteria will load into their respective fields. You may modify the search criteria if you wish. Once your criterion is in place, use the [Submit] button to execute your search.

If you want to remove a saved Protocol Search from the system, select it and then click the [Delete] button at the far right. If you have modified the search and want to save it under the same name, you can click the [Update] button to do so. If you have modified the search and want to save it under a different name, you can click the [Save As] button and enter the name of the new saved search.

Protocol Searches that have been saved are displayed on the Saved Searches widget on the Home page.
PART VII: Subject Search

In this section, you will learn about the subject search function of JeffTrial.

The Subject Search section of JeffTrial allows you to find a specific subject or subjects based upon a variety of criteria. Report results can be exported to PDF or Excel formats.

The Subject Search page is accessed by the Subjects ➔ Subject Search menu item. The page provides multiple fields for entering search criteria. Several fields are labeled Multi-Select, allowing more than one value to be considered a ‘match’ when conducting a search.

The search criteria fields are arranged into sections. To aid visibility, some section headings include [+ ] and [-] hyperlinks to display and undisplay the section’s fields.

You may use any number of fields from any combination of sections to define the criteria for your protocol search. After entering your criteria, click the Search button to generate a list of matching subjects.

Subjects ➔ Subject Search

Search criteria may be removed from all fields by clicking the Clear button.
**Subject Search Options**

*Filter Type*

Filter Type radio buttons are available throughout the Subject Search page and may be used to refine your search criteria:

![Filter Type](image)

To include subjects that have *any* of the selected criteria, select the ‘Contains Any (OR)’ radio button. To include protocols that meet *all* of the criteria listed, select the ‘Contains All (AND)’ radio button. To *exclude* protocols that meet the selected criteria, select the ‘Does Not Contain’ radio button.

*Search Results*

Search results vary depending upon inclusion criteria. The following screenshot is an example of Subject Search results:

![Search Results](image)

The header displays the search criteria used. Column headers are hyperlinks. Clicking a column header hyperlink will sort the results based on the data in that column (by default, sorting is alpha/numeric based). A subsequent click on the column header hyperlink will sort in ‘reverse’ order.

In the body of the report, each row represents one subject. Sensitive patient information may be hidden for the subjects you do not have the required privileges to view. Subject IDs are usually displayed as hyperlinks. Selecting a
hyperlink brings you to the Subject Console → Demographics tab for that subject. If no hyperlink is available, you do not have the privileges required to view the protocol.

You may change the number of results available by selecting a different value from the Page Size drop-down menu. An additional filter may be applied to reduce the results by typing any filter criteria. Finally, the results page number may be selected or you may scroll through the pages by clicking the arrows available to you.

The bottom section of the result page displays the number of subjects matching the search criteria, and buttons to view or export the data in different formats.

Clicking on the [Back to Search] button takes you back to the search page where you may modify your search. Clicking on the [View Excel] button will transfer the results to an Excel spreadsheet. Clicking on the [View PDF] button will create a PDF version of the results.

**Configuring Search Result Display**

By default, the results display the following fields: Subject ID, Last Name, First Name, Protocol No., and Additional Protocol Numbers (which this subject is associated with). By checking the checkbox to the left of a search field, the data for that field will be included in the results. The field does not need to be used as part of the search criteria.

Checkboxes that are checked and disabled are required for the output and will always be shown. Checkboxes that are checked on the main Subject Search page can be cleared by clicking the [Unselect] button.
Subject Search Criteria Fields

Subjects are found based upon the search criteria entered into the Subject Search fields. The following sections explain how these fields are used.

Remember - multiple fields can be selected for an individual search. Selecting multiple fields will narrow the search results; all of the search criteria need to be met before the subject will be selected for the result list.

Subject Demographics

The fields in the Subject Demographics section refer to data stored on the Subject → Subject Console → Demographics:

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Name</td>
<td>This field matches subjects whose last name starts with the characters entered. For example, an entry of ‘ols’ will match ‘Olson’ but not ‘Nichols’</td>
</tr>
<tr>
<td>Birth Date</td>
<td>Matches subjects having the entered Birth Date</td>
</tr>
<tr>
<td>Expired Date</td>
<td>Matches subjects with an Expired Date in the date range entered. The From Date and Thru Date fields may be used together or independently. When From Date or Thru Date is left empty, the search assumes there is no lower or upper bound to the date, respectively.</td>
</tr>
<tr>
<td>Race</td>
<td>Matches subjects with the selected Race. A subject with multiple recorded races is matched when any of their races matches this field.</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Matches subjects with the selected Ethnicity</td>
</tr>
<tr>
<td>Gender</td>
<td>Matches subjects with the selected Gender</td>
</tr>
<tr>
<td>Last Date Known Alive</td>
<td>Matches subjects with a Last Date Known Alive in the date range entered. The From Date and Thru Date fields may be used together or independently. When From Date or Thru Date is left empty, the search assumes there is no lower or upper bound to the date, respectively.</td>
</tr>
</tbody>
</table>
**Subject Status**

Searching based on Status will show subjects with the selected status at any point during the date range:

The status of a subject changes as the subject moves through the protocol, typically according to the following sequence:

1. Consented
2. On Study
3. On Treatment
4. Off Treatment
5. On Follow-Up
6. Off Study
7. Expired

Searching based on **Status Change To** will match subjects whose status was changed to that status during the date range.

If the Thru Date isn’t used, the search will match subjects whose status changed to the specified status on or after the From Date. If the From Date isn’t used, the search will match subjects whose status changed to the specified status prior to or on the Thru Date.

**Consent and Eligibility**

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent Signed Date</td>
<td>Matches subjects with a Subject Console &gt; Consent tab, Signed Date in the date range entered. The subject’s earliest consent Signed Date is used for the search. The From Date and Thru Date fields may be used together or independently. When From Date or Thru Date is left empty, the search assumes there is no lower or upper bound to the date, respectively.</td>
</tr>
<tr>
<td>Eligibility Verified Date</td>
<td>Matches subjects with a Subject Console &gt; Eligibility tab, Status Date in the date range entered. The From Date and Thru Date fields may be used together or independently. When From Date or Thru Date is left empty, the search assumes there is no lower or upper bound to the date, respectively.</td>
</tr>
<tr>
<td>Eligibility Status</td>
<td>Matches subjects who currently have the selected eligibility status.</td>
</tr>
</tbody>
</table>
**On Study**

The fields in the On Study section (primarily) refer to data stored on the Subject ➔ Subject Console ➔ On Study:

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sequence No.</td>
<td></td>
</tr>
<tr>
<td>Institution Type</td>
<td></td>
</tr>
<tr>
<td>On Study Site</td>
<td></td>
</tr>
<tr>
<td>Follow-Up Study Site</td>
<td></td>
</tr>
<tr>
<td>On Study Date</td>
<td></td>
</tr>
<tr>
<td>Initial On Treatment Date</td>
<td></td>
</tr>
<tr>
<td>Disease Site</td>
<td></td>
</tr>
<tr>
<td>Histology</td>
<td></td>
</tr>
<tr>
<td>Primary Diagnosis</td>
<td></td>
</tr>
<tr>
<td>Secondary Diagnosis</td>
<td></td>
</tr>
<tr>
<td>Subject W00</td>
<td></td>
</tr>
<tr>
<td>Staff Name/Role and Scope</td>
<td></td>
</tr>
<tr>
<td>Treating Physician</td>
<td></td>
</tr>
</tbody>
</table>
Protocol

The fields in this section refer to data stored in various PC Console → Main tabs. Subjects associated with the protocols that meet the specified criteria are matched:

<table>
<thead>
<tr>
<th>Field</th>
<th>Filter Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol No.</td>
<td></td>
</tr>
<tr>
<td>Department</td>
<td></td>
</tr>
<tr>
<td>Phase</td>
<td></td>
</tr>
<tr>
<td>Age Group</td>
<td></td>
</tr>
<tr>
<td>Protocol Type</td>
<td></td>
</tr>
<tr>
<td>Scope</td>
<td></td>
</tr>
<tr>
<td>NCI Trial ID</td>
<td></td>
</tr>
<tr>
<td>Program Area</td>
<td></td>
</tr>
<tr>
<td>Sponsor</td>
<td>Principal Sponsor Only checkbox</td>
</tr>
<tr>
<td>Sponsor Type</td>
<td></td>
</tr>
<tr>
<td>Sponsor Role</td>
<td></td>
</tr>
<tr>
<td>Oncology Group</td>
<td></td>
</tr>
<tr>
<td>Scope</td>
<td>Management Group</td>
</tr>
<tr>
<td>NCI Trial ID</td>
<td>Summary 4 Report Type</td>
</tr>
<tr>
<td>Program Area</td>
<td></td>
</tr>
</tbody>
</table>
**Follow-Up**

The fields in the Follow-Up section refer to data stored in the Subject Console ➔ Follow-Up tab:

<table>
<thead>
<tr>
<th>Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Off Treatment Date</td>
</tr>
<tr>
<td>Off Treatment Reason</td>
</tr>
<tr>
<td>Off Study Date</td>
</tr>
<tr>
<td>Off Study Reason</td>
</tr>
<tr>
<td>Last Follow-Up Date</td>
</tr>
<tr>
<td>Last Known Survival Status</td>
</tr>
</tbody>
</table>
Saved Subject Searches

Search criteria that are used often may be saved to increase your searching productivity in the future.

After you have created a Subject Search that you would like to be able to run again, you can save it by clicking the [Save As] button near the top of the page. A prompt box will pop up where you can enter a name for the search and then click the [Save] button.

To recall a saved Subject Search, select it in the Saved Searches field. The search name will display, and the saved search criteria will load into their respective fields. You may modify the search criteria if you wish. Once your criterion is in place, use the [Submit] button to execute your search.

If you want to remove a saved Subject Search from the system, select it and then click the [Delete] button at the far right. If you have modified the search and want to save it under the same name, you can click the [Update] button to do so. If you have modified the search and want to save it under a different name, you can click the [Save As] button and enter the name of the new saved search.

Subject Searches that have been saved are displayed on the Saved Searches widget on the Home page.
PART VIII: Reports

JeffTrial allows you to create various reports. The number of reports you can create will vary depending on your user role within the system. However, everyone can find the Reports page under “Reports” in the menu bar:

Menu Bar:

![Menu Bar Image]

Reports ➔ Reports

*More information on how to create reports will come at a later time.*