

Reporting and Searching

Protocol Search

Protocol Search is a robust searching tool. You specify the search criteria and which protocol data to display in the search results. Search results may be captured in a PDF report or Excel spreadsheet.

1. Open the Protocol Search page via the **Protocols → Protocol Search** menu item.

The Protocol Search page provides dozens of data fields. To search, you enter data into fields to indicate which protocol data you wish to match, then click the **Search** button. You may enter as many data items as you wish.

2. Click the **Completed** checkbox in the upper section, then click the **Search** button.

The top of the results page lists the criteria used in the search.

If there are a great deal of matching protocols, navigational aids are provided to display the next (and previous) page of results, jump to a particular page, or filter the matching data (text entered into the **Filter:** field will limit the found results to those having the text in any of their columns).

Below this is a table of matching protocols, each protocol listed in its own row. Column headers are hyperlinks, and selecting them will cause the results to be sorted by that column's data (selecting a column again sorts the data in 'reverse' direction).

Protocol No. column values are hyperlinks. Selecting the link will jump you to that protocol in the **PC Console**.

The bottom of the results page reports a count of the number of protocols found.

The **View Excel** button creates an Excel spreadsheet with the search result data. The **View PDF** button creates a PDF document with the search results.

The **Back to Search** button returns to the **Protocol Search** page.

3. Return to the **Protocol Search** page.

Note that the criteria used in the last protocol search is automatically filled in. The **Clear** button is provided to remove any previously-selected items.

4. Click the **Clear** button.

The Protocol Search page is divided into expandable sections. Each section has a header with a **[+]** hyperlink and a section name. To open a section, click its **[+]** hyperlink.

5. Click the **[+]** hyperlink to open the **Main** section.

More search criteria fields are displayed. You should see a list of fields related to the Main information of protocols.

On the left are **Result Column** checkboxes. These may be selected to include additional data columns on the search result page.

6. Click the **Completed** checkbox in the upper section.

In the **Main** section, click in the **Phase** field to display a list of choices. Choose **Phase II** studies.

Clicking in the field again will allow you to select another choice, expanding your search.

In the **Main** section, click the **Result Column?** checkbox for **Protocol Type**.

The checkboxes allow you to customize the data that appears in the search results.

Click the **Search** button.

In the Protocol Search Results page, the header indicates that this is a list of Phase II protocols that are Completed (Abandoned, Terminated, or IRB Study Closure). In the table of results, a column for the Protocol Type is now included.

7. Use the **Back to Search** button to return to the Protocol Search page.

Some search criteria can be a bit more complex. At the top of the page is the **Status** field. To use this field, you must specify a status and date criteria. If you provide a **From Date** and a **Thru Date**, you are indicating that you wish to see protocols that had that status *at any time* during the date range.

Supplying only a From Date matches protocols having that status at any time after the From Date, while supplying only a Thru Date matches protocols having that status at any time previous to the Thru Date.

8. In the Status field, select **Open To Accrual**.

In the corresponding **From Date**, enter **01/01/2007**.

In the corresponding **Thru Date**, enter **12/31/2007**.

(It is assumed that the previous search criteria are still in place.)

Click the **Search** button.

Your previous results have now been narrowed to those **Phase II** protocols that were **Open To Accrual** at some point in **2007** and are currently marked as **Completed**.

9. Return to the Protocol Search page.

Similar to the **Status** field, there is a **Status Change** field at the top of the Protocol Search page. When this field is used, the search returns protocols that had their status *changed to* the selected status at some point during the date range.

The final section of Protocol Search is labeled **Accrual**. It includes checkboxes to display the protocol accrual grouped by all affiliates, the research center, and the VA. The section has From Date and Thru

Date fields for limiting the accrual period (otherwise, the lifetime protocol accrual is shown). These dates can be used by themselves or in conjunction with the Status and Status Change date ranges.

Protocol Search criteria can be saved and saved searches can be found and run quickly. After you have developed and tested search criteria that you like and will use over and over, you can save the search to avoid remembering and entering all of the criteria again. (Dates that you enter are saved as the calendar date, however, and are not saved as a relative date. Entries like 'YB', are not re-evaluated each time the saved search is picked.)

10. Click the **Save As...** button (found at the top of the page).
11. Enter a name for your search in the **Name** field and click the **Save** button.

Your saved searches will be available in the **Saved Searches** drop-down field at the top of the page. They will also display in the **Saved Searches** widget on the **Home** page.

Subject Search

Subject Search is another robust searching tool, with capabilities identical to **Protocol Search**. It is available via the **Subjects** → **Subject Search** menu item. It returns a list of subjects that meet specified criteria; the same subject may appear in the search results multiple times when they are on multiple protocols.

Reports

OnCore has many standard reports. We'll review a few of them and leave the rest to you as a self-learning exercise. Reports are documented in the product overview documentation.

Planned Visits Report

The **Planned Visits Report** shows a list of subject visits for a date range and can be filtered by Protocol, Procedure, Subject Staff, Organizational Unit, and Management Group. It is available via the **Reports** → **Reports** menu item in the **Planned Visits** section.

1. Open the **Planned Visits Report** criteria page via the **Reports** → **Reports** menu item. Use the vertical tab to display the Planned Visits report group.
2. Enter the following criteria and click the **Submit** button.
 - **Visit Date From:** 01/01/2011
 - **Visit Date Thru:** 12/31/2011
 - **Protocol No:** <your protocol>

The results display all visits for your protocol during the date range. The hyperlink in the **Visit Info** column will jump you to the **Subject Visit Update** page where you can verify the visit and enter visit information.

Oncology Reports

OnCore has several reports that are specific to the oncology area of clinical trials. These reports are available via the **Reports → Reports** menu item in the **Accrual Monitoring – Oncology Only** section. There are a number of **Summary 3** and **Summary 4** reports.

In addition, there are related *discrepancy* reports used to assist in assuring that your Summary 3 and Summary 4 reporting is accurate. The Discrepancy reports point out protocols and subjects that have data to may need to be fixed in order for them to be included in Summary 3 and Summary 4 reporting. We recommend that the discrepancy reports be run periodically to find and fix inaccurate or incomplete data.

Accrual Monitoring Console

The **Accrual Monitoring Console** provides a quick means to view protocol accrual information categorized by Oncology Group or Department, Management Group, Principal Investigator, or Subject Staff.

How To Use the Console

1. Open the console via the **Reports → Accrual Monitoring** menu item.

The top of the page contains two date entry fields. Both of these must be filled in to use the Console.

Along the left side are the four different categories. Each category contains a hyperlink tab and/or a Find-As-You-Type data entry field. After the dates have been entered at the top, clicking a tab or selecting an entry will launch a search.

The search results are displayed in the main area to the right.

2. Enter a **From Date** of **01/01/2007** and a **Thru Date** of **12/31/2007**.

These dates indicate that you are looking for accruals that have occurred during the 2007 calendar year.

3. Click the **By Scope** tab in the **Management Group** section.

A search is done for all protocols that were open to accrual in the date range. The results list the number of protocols and number of accruals during that range. Data is categorized by the scope (defined in the PC Console → Main → Details tab), and then further divided for each Management Group.

4. Select the **By Sponsor Type** tab in the **Management Group** section.

Again, a search is done for all protocols and accruals in the date range. This time, the results are categorized by the type of principal sponsor (defined in the PC Console → Main → Sponsor tab), and then further divided for each Management Group.

5. In the **Protocol Accrual For** Find-As-You-Type field in the **Management Group** section, select **Lung**.

A search is done for all protocols that were open to accrual in the date range and have the selected Management Group chosen in the PC Console → Main → Management tab.

In this case, individual protocols are listed, and have some summary accrual information displayed:

- The **Summary Accrual** section displays the accrual counts for this protocol during the entire time the protocol has been open up to the time the report is run (not just for the date range entered).
- The **Period Summary Accrual** section displays the accrual counts for this protocol during the date range entered.
- The **Period Accrual** section also displays the accrual counts by month during the selected time period. (Those protocols marked as Summary Accrual Info Only in PC Console → Main → Details will not have accrual counts displayed in the this section since the accruals are entered over a variable timeframe.)

Additional Information about Searching

When searching by **Management Group**, a protocol will only be counted according to its primary Management Group.

Checking the **Therapeutic Protocols Only** checkbox in the upper section will reduce the resulting protocols to only those with a Protocol Type (PC Console → Main → Details → Protocol Type) where the parent type is defined as **Therapeutic** in the Reference Codes.

When changing the date range or the Therapeutic Protocols Only checkbox, the **Refresh** button must be clicked to perform a new search.

Exporting the Search Results

The **View Excel** button creates an Excel spreadsheet with the search result data.

The **View PDF** button creates a PDF document with the search results.

The **View Chart** button displays a bar chart with the results. (Because of the different configurations of search results, a bar chart is not always available.)

DSMC Console

The **DSMC Console** is intended to assist DSMC reviewers when reviewing protocols. It consolidates and displays captured data, and provides a means to export this data for use by products like Microsoft Word. It is a very useful (and unique) view of a protocol's information.

1. Open the DSMC Console by selecting the **Reviews** → **DSMC Console** menu item.
2. Select your protocol in the **Select Protocol** Find-As-You-Type field.

Your protocol will load into the console and its information will be displayed. On the left, vertical tabs can be clicked to present various protocol information. Some of these tabs present information that is only available here, like the **Accrual History**, **Disposition**, **Baseline Demographics**, **Response**, and **Survival/TTP** tabs.

The **Export** tab allows you to select which tab information you would like to exported to a **Rich Text Format (RTF)** document that can be opened in Microsoft Word.