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Protocol Reports and Search Tools

Using Protocol Search

Protocol Search is a robust searching tool that allows you to specify search criteria and then choose additional protocol data to appear in the search results. You can export your search results to a PDF report or Excel spreadsheet.

Conduct a protocol search

   As you can see, the Protocol Search page provides dozens of data fields, allowing for complex and detailed searches.

2. In the Protocol Status section, locate the Status and Status Change fields.
   The Status field allows you to search for protocols that had a specific status at some point during a time range.
   The Status Change field allows you to search for protocols that changed to a specific status during a time range.

3. Select your desired protocol Status (for example, Open to Accrual).

4. Enter a From Date (for example, t for today’s date and leave the Thru Date blank).
5. Click **Search**. The Protocol Search Results page appears with your search criteria listed in the page header.

The Protocol Count shows how many protocols match your search criteria. As of today, there are 178 open protocols in this environment:

![Protocol Search Results](image)

**The search criteria you used is always visible in the header of the results page**

**The Protocol Count shows you how many studies match your search criteria**
Add more criteria to a protocol search

After running a search, you might decide that you’d like to narrow your results further.

1. **Click** **Back to Search**.
   The criteria you used is still selected in the Protocol Search page.

2. In the **Staff Name** field, select the name of a staff member (for example, one of the principal investigators).

3. In the **Staff Role** field, select the staff member’s role (for example, **Principal Investigator**).

4. **Click** **Search**.
   In this example, only the PI Grace Applewood’s protocols now appear in the search results.

---

**Can I see a list of Grace Applewood’s open protocols?**

**The search criteria you used is always visible in the header of the results page.**
Add more columns to your search results page

The search criteria determine which protocols appear in the results page. It might be helpful to see more information about these protocols. If so, you can select additional columns to display.

1. Click Back to Search.

2. The search criteria you used are retained in the Protocol Search page.

3. Click the [+] next to the Main section.

4. Additional fields are now visible in Protocol Search. These fields can be used to further refine your search results, or these fields can be included as columns on the results page.

5. Select the checkboxes for desired fields, for example, Phase and Protocol Type.

6. Click the [+] next to the Accrual section.

7. Select the checkboxes for Total Accrual and Protocol Target Accrual to show these fields in the results.

8. Click Search.

9. The same number of protocols appear in the search results because you did not add any additional criteria, but more information is visible on the results page:
<table>
<thead>
<tr>
<th>Protocol No.</th>
<th>Additional Protocol Numbers</th>
<th>Department</th>
<th>Title</th>
<th>PI Name</th>
<th>Current Status</th>
<th>Current Status Date</th>
<th>Phase</th>
<th>Protocol Type</th>
<th>Total Accrual</th>
<th>Protocol Target</th>
<th>Protocol Score</th>
<th>Add Staff?</th>
<th>All Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAR0775</td>
<td>2015401; 2015801; 5301; 5599; 5982</td>
<td>Cardiology</td>
<td>Evaluation of Exercise Treadmill Test Indices in Patients With Cardiovascular Disease</td>
<td>Applewood, Grace</td>
<td>OPEN TO ACCRUAL</td>
<td>10/08/2012</td>
<td>II</td>
<td>Gene Therapy</td>
<td>12</td>
<td>27</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MED0939</td>
<td></td>
<td>Orthopedics</td>
<td>A Randomized Controlled Trial of Regenex SD versus Exercise Therapy for Treatment of Non-retracted Supraspinatus Tendon Tears</td>
<td>Applewood, Grace</td>
<td>OPEN TO ACCRUAL</td>
<td>11/11/2016</td>
<td>II</td>
<td>Outcomes</td>
<td>0</td>
<td>400</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STRAT1016</td>
<td>GOV00490.17-IRB2016.0904</td>
<td>Cardiology</td>
<td>A clinical trial to evaluate treatments using ivacaftor for patients with Cystic Fibrosis</td>
<td>Applewood, Grace</td>
<td>OPEN TO ACCRUAL</td>
<td>06/30/2016</td>
<td>II</td>
<td>Outcomes</td>
<td>0</td>
<td>225</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Add staff to protocols from the search results page

Protocol Search can be used to identify protocols to which certain staff members should be assigned. Remember that protocol staff assignments can be used to send notifications, to assign tasks in a task list, and for security purposes. Once the appropriate protocols have been identified, one or more staff members can be assigned to those protocols in bulk.

1. Select the checkbox in the Add Staff? column for the relevant protocol.

2. If desired, you can select all protocols in the search results page at once, using the All link in the Add Staff? column header.

3. Click the Add Staff button.

4. Select the staff member you’d like to add in the Staff Name field.

5. Select the staff member’s role in the Staff Role field.

6. Enter a Start Date.

7. Click Submit.

The staff member is now assigned to the protocol.

NOTE: Protocol Search cannot be used to remove staff from protocols. If a staff person leaves your organization and you want to remove the person from all protocols (or replace them with a different staff person), you can do this in the Admin > Contacts > [contact] > Protocol Assignments section and the Admin > Contacts > [contact] > Subject Assignments section.
Conduct a protocol search using date ranges

Searches using date ranges can be more complicated. In the Protocol Status section, for example, the Status field requires that you first choose a status, and then enter date criteria as follows:

- To match protocols having the selected status within a specified date range, enter both a From Date and a Thru Date.
- To match protocols having the selected status at any time after the From Date, leave the Thru Date blank.
- To match protocols having the selected status at any time prior to the Thru Date, leave the From Date blank.

The following instructions show you how to limit your previous search to only those protocols that were Open to Accrual at some point in the last year.

1. Click Back to Search to return to the Protocol Search page.

2. Clear your search selections using the button at the bottom of the page.

3. In the Status field, select Open to Accrual from the drop-down list. In the corresponding date fields, enter the following date shortcuts:
   - From Date: yb-2 (indicating the beginning of the current calendar year, minus two years)
   - Thru Date: ye-1 (indicating the end of the current calendar year, minus one year)

4. Click Search.
   
   All protocols that were open at some point during that date range appear in your results. This includes protocols that were open the entire time, protocols that were open prior to January 1st of two years prior but closed during the specified time window, and new protocols that opened for accrual between January 1st of two years prior and December 31st of one year ago.

5. Click Back to Search.
6. Clear your search selections using the button at the bottom of the page.

7. In the **Status Change** field, select **Open to Accrual** from the drop-down list. In the corresponding date fields, enter the **same** date shortcuts:
   - **From Date**: \(yb-2\) (indicating the beginning of the current calendar year, minus two years)
   - **Thru Date**: \(ye-1\) (indicating the end of the current calendar year, minus one year)

8. Click **Search**.

   You will see fewer protocols in your search results. Now, only protocols that **changed to** Open to Accrual during that date range appear in your results.
Save a protocol search

You can save protocol search criteria to perform searches more efficiently. After you have developed and tested searches that you know you will use frequently, you can save the search to run it again without having to reenter all the search criteria.

**NOTE:** Any dates that have been entered as part of the saved search are saved as the calendar date and not a relative date. Date entries using shortcuts such as “yb” are not re-evaluated each time a saved search is selected.

1. Click **Back to Search** to return to the Protocol Search page.

2. At the top of the page, click the **Save As…** button.

3. In the pop-up window, type a name for your search in the **Name** field and click **Save**.
   
   Your saved searches will be available in the drop-down list attached to the Saved Searches field. They will also appear in the Saved Searches widget on the Home page.

Share a protocol search

When creating a new saved search, you can share it with other users. To do so, click **Share** in the **New Saved Search** window and select the desired user(s) in the **Staff Name** multi-select field.

The selected users will now see a link to the shared search in the Searches widget on their home screen.
Navigate back to your protocol search results

Sometimes the results page of a Protocol Search ends up like a “working list” of protocols that need your attention.

If you click on any protocol number in your search results page, the protocol will open in the PC Console.

1. Once you have entered your criteria, click Search.

2. Click any Protocol No. link in the search results page.
   You are now in the PC Console and can make the appropriate updates to this protocol record.

   You are returned to the search results page and can continue working on additional protocols in the list.
Using Document Search

Document Search allows you to easily locate protocol documents. Document Search locates files that have been attached in one of the following locations:

- PC Console > Documents/Info > Attachments tab
- IRB or PRMC/SRC Reviews (if the documents are marked as Released)
- PC Console > Institution > [institution] > Documents tab

**NOTE:** Document Search displays documents only from *active* protocols, that is, protocols with a status of Open to Accrual, Closed to Accrual, or Suspended. Documents associated with inactive protocols cannot be found using Document Search.

**Document Search criteria**

Search criteria are entered in Protocols > Document Search. You can use any of the options, alone or in combination, to narrow results.
Conduct a document search

1. Navigate to **Protocols > Document Search**.
   An Institution is required; this field will default to the institution to which your contact record is associated. You can only select institutions to which you have access.

2. In the **Keyword** field, type a relevant protocol keyword and click **Submit**.
   Searching for a keyword (such as “lung,” for instance) will display protocols for which that word appears in the Title, Short Title, or Objectives field. (The keyword field doesn't filter documents, only protocols.)
   By default, the Document Search Result page displays *the most recent version* of each type of document attached to the protocols returned by the search.
   Remember that only protocols with an active status (Open to Accrual, Closed to Accrual, or Suspended) will appear in the search results.

3. Click any of the **File Name** links to download the .doc or .pdf files.

4. Click **Back**.

5. Select the **Display All Documents** checkbox.
   This checkbox will display *all versions* of each document type, in case you (or your end users) need to download an old version of a consent form or other protocol document.

6. Click **Submit**.
   If any of the document types have previous versions that have expired or been replaced by newer versions, those will now be visible and downloadable.
The Expiration Date will appear in red for each expired document if the DOCUMENT_SEARCH_EXPIRATION_DATE configuration is set to Y.

Select the Display All Documents checkbox to see previous versions of each document, as well as the latest version.
The documents that do appear in Document Search results include:

- Documents attached to IRB or PRMC reviews that have the Released checkbox selected
- Documents uploaded to the PC Console > Documents/Info tab
- Documents uploaded to the PC Console > Institution > [institution] > Documents tab

Documents uploaded to the following places do not appear in Document Search:

- Documents attached to tasks in a Task List
- Documents uploaded to the Coverage Analysis Console
- Documents uploaded to the Financials Console
- Documents uploaded to the Subject Console > Documents/Info > Attachments tab
- Documents attached to an organization record (an institution, lab, or IRB)

What security features affect Document Search results?

Search results are limited by both your organization access and the scope of your permissions. If you have access to the Research Institution (either specified in your contact record > Organization Access field, or by additional protocol organization access granted for certain studies), then Document Search results include documents from the PC Console > Documents/Info > Attachments page.

Otherwise, you will see documents that have been uploaded to your institution’s Documents tab. The permission that controls Document Search can further limit access by organizational unit, department, management group, or assignment as staff on the protocol.
OnCore Standard Reports

OnCore provides many standard reports that have been developed in collaboration with our customers.

You can also upload custom reports to run in OnCore, which is covered in detail in the Reporting and Searching: Advanced section of this training manual.

The following instructions show you how to run one example report with protocol information: the IRB Lapse Report.

Note to Oncology users

See the Learning Portal's Accrual Monitoring Reports/Oncology Only page for detailed Data Table 3 and 4 Reporting options. OnCore provides Data Table 3 protocol and subject discrepancy reports that identify data gaps, which allows you to ensure the accuracy of your reporting.

Run the IRB Lapse Report

The IRB Lapse Report can be used to identify protocols whose latest IRB review has already lapsed that need to be re-reviewed right away, or protocols whose latest IRB review will lapse in the future. This report can help you follow up on protocols that are delinquent, or proactively identify protocols that need to be re-reviewed at an upcoming IRB meeting.

NOTE: There is an identical report for PRMC reviews called the PRMC Lapse Report.

1. Navigate to Reports > Reports and click the IRB group on the left.

2. In the Standard Reports section, click the IRB Lapse Report link.

3. Enter the following criteria:
   - From Date
   - Thru Date
• Organizational Unit

4. Click **Submit**.

The results list all protocols whose latest IRB review will expire within the next six months.
When searching for recent expiration dates, the Lapse Days reflects how many days overdue the protocol is today (or at the end of the date window specified)

<table>
<thead>
<tr>
<th>Protocol No.</th>
<th>Current Status</th>
<th>PI Name</th>
<th>PM Name</th>
<th>CRA Name</th>
<th>IRB No.</th>
<th>Lapse Date</th>
<th>Next Approval Date</th>
<th>Lapse(Days)</th>
<th>Accrued During Lapse Period</th>
<th>No. of Subjects On Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSMBANK</td>
<td>OPEN TO ACCRUAL</td>
<td>Investigators Irene</td>
<td>Bonner, Chloe</td>
<td>IRC5984</td>
<td>09/15/2016</td>
<td>68</td>
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<td>0</td>
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<td>CAR0000</td>
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<td>Allen, Heather</td>
<td>C</td>
<td>IRC5984</td>
<td>06/16/2016</td>
<td>159</td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>0</td>
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<td>Bonner, Chloe</td>
<td>L</td>
<td>IRC5984</td>
<td>06/11/2016</td>
<td>174</td>
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<td>1</td>
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<td>NM0130</td>
<td>OPEN TO ACCRUAL</td>
<td>Bookman, Carrie</td>
<td>D</td>
<td>IRC5984</td>
<td>06/2/2016</td>
<td>173</td>
<td>0</td>
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<td>Duerst, Quincy</td>
<td>D</td>
<td>IRC5984</td>
<td>06/3/2016</td>
<td>172</td>
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<td>D</td>
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<td>0</td>
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<td>D</td>
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<td>06/17/2016</td>
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<td>ONC2233</td>
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<td>IRC5984</td>
<td>06/3/2016</td>
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<td>D</td>
<td>IRC5984</td>
<td>06/17/2016</td>
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<td>06/19/2016</td>
<td>159</td>
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</tr>
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