Adding Participating Sites to Abbreviated Trials

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Adding Your Site to Industrial Trials

You can add your organization as a participating site to any Abbreviated trial that meets the following criteria:

(To add your organization as a participating site to a Complete trial, contact the lead organization.)

| Trial Attribute | Requirement |
|-------------------------|--|
| Lead Organization | Not an organization in RSS |
| Your Organization | Not currently participating in the trial |
| Trial Processing Status | Accepted or beyond |

Once added, you can update your site's record at any time.

Trial information that you can update after adding your site includes the following:

- · Organization's local trial identifier
- Site principal investigator
- Organization family's program codes
- Site recruitment status and dates

How to Add Your Organization as a Participating Site

- 1. Select the trial that your site is participating in. The **Available Actions** column in the search results table displays actions currently available for the trial.
- In the Available Actions column, click the Select Action button and click Add My Site. The Add Participating Site page appears. The Participating Site list contains all organizations in the Organization Family associated with your CTRP account.
- 3. From the Participating Site list, select the organization that you want to add to this trial. Click Next. Another Add Participating Site page appears.
- 4. In the **Local Trial Identifier** field, enter the identifier used at the participating site.
- 5. Next to the Site Principal Investigator field, click Look Up to search for and select the site principal investigator.
- 6. (Optional) Specify a contact for the trial at this participating site. You can do so in one of the following ways:
 - Next to the Site Primary Contact field, click Look Up to search for and select the site primary contact.
 - Next to the Generic Contact field, click Look Up Generic Contact to search for and select a CTRP person record.
- 7. (Optional) Consider whether the default contact information for the selected person record is appropriate for the trial at this participating site. The system accepts either the contact's primary telephone number or the contact's primary email address. You can provide both if available. Enter the phone number in the format 123-456-7890. You can provide an extension if available.
- (Optional) In the Program Code field, select one or more program codes for the trial. The Program code field lists all program codes available for the organization family.
- 9. Add site recruitment status information:
 - a. Select or enter the appropriate information in the text fields and drop-down lists. The following table describes the fields. An asterisk (*) indicates a required field.

| Field | Description/Instructions |
|--|--|
| Site Recrui tment Status Date* | Enter the date on which the current trial status became effective. To ensure that you record valid status dates, review the information provided in CTRP System Rules for Study Status and Dates. |

Site Recrui tment Status Select the current stage or state of the trial or study.



The system validates all status transitions when you save a status record. If you add or update a status transition that does not conform to the rules provided in Status Transition Rules, the system displays errors and/or warnings. *Warnings* indicate that fixing the status record is optional; you do not have to resolve the transitions. However, *Errors* indicate that you must resolve the transitions by correcting trial status records.

- b. Click Add Status. The Site Recruitment Status History section appears, displaying the site recruitment information you entered.
- c. Repeat the process of entering a status date, entering a status, and clicking Add Status until you have entered all statuses for the site.
- 10. If the system displays Errors or Warnings indicating that the status you added is invalid, do one of the following.
 - a. To edit the status, in the **Actions** column, click the **Edit** icon. Then, in the **Edit Trial Status** dialog box, make changes as indicated in the Error and/or Warning message.
 - b. To delete the status, in the Actions column, click the Delete icon. Enter a comment indicating the reason why you deleted the record. Then add the correct status information.
- 12. Click Save. Your information is added to the trial details.

Adding Multiple Sites to Industrial Trials - for Registration Administrators

As a site administrator, you can add participating sites as follows:

- · Add your site to multiple Abbreviated trials
- Add a Family Member Organization as a participating site to multiple Abbreviated trials
- Add multiple Family Member Participating Sites to a given trial



The system does not allow duplicate sites on trials.

How to Search for the Trials to which You Want to Add Participating Sites

- 1. On the toolbar, click **Register Trial > Add Sites**. The Search Trials page appears.
- 2. Enter a trial identifier (NCI, lead organization, or other) or enter all or part of a trial title.
- 3. Click **Search**. The system lists in the results table the *Abbreviated* trials with which your affiliated organization or its family members are not yet participating.



The system can return up to 100 trials. If the system finds over 100 records in the database, it prompts you to narrow your search criteria.

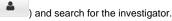
4. Optionally, to sort the results, click the column ascending or descending arrows. This option is available only prior to adding your first site.

How to Add Organizations as Participating

- 1. On the toolbar, click **Register Trial > Add Sites**, and search for the trials to which you can add participating sites as described above. The *Abbreviated* trials with which your affiliated organization or its family members are not yet participating are listed in the results table.
- 2. In the row of the trial to which you want to add sites, click the **Plus** sign (). The trial record expands to display trial information. The Site field is pre-populated with your affiliated organization automatically.

 For an Abbreviated trial where the participating site you are adding is a member of a cancer center family, the Program Code(s) field is available.
- The Program Code field lists all program codes available for that organization family.

 3. Optionally, in the **Program Code(s)** field, select one or more program codes for the trial.
- 4. If you need to change the participating site, select one from the Site drop-down list. Only your family member organizations are listed.
- 5. If the Principal Investigator has not been selected, click the Look Up Person icon (



- 6. Enter the Local Trial Identifier.
- 7. (Optional) If the trial record does not already specify a contact for the trial at this participating site, you can do so in one of the following ways:
 - Next to the Site Primary Contact field, click the look up person icon to search for and select the site primary contact.
 - Next to the Generic Contact field, click the look up person icon to search for and select a CTRP person record.
- 8. (Optional) Consider whether the default contact information for the selected person record is appropriate for the trial at this participating site. The system accepts either the contact's primary telephone number or the contact's primary email address. You can provide both if available. Enter the phone number in the format 123-456-7890. You can provide an extension if available.
- Select the Site Recruitment Status and the Site Recruitment Status Date. Click Add Status. The status record appears in the Site Recruitment Status History list.
- 10. If your organization belongs to a family, you can add to this trial any site within that family. To add another site to the same trial, in the **Site** column, click **Add Another Site**, and repeat the steps above to complete the trial/site information.
- 11. Scroll to the bottom of the page and click Save.