Abstracting NCI-Specific Information - Include v4.5

NCI-Specific Information applies to *Complete* and *Abbreviated* trials. For *Abbreviated* trials, indicate whether or not the trial is Industrial.

> Trial categories are now referred to as Study Sources. Refer to https://cancercenters.cancer.gov/GrantsFunding/eData#dt4 for further information about terminology for NCI-Specific and Data Table 4 information.

Included in this section is the option, for certain trials, to include them in, or exclude them from, the batch of trials that CTRP sends to ClinicalTrials.gov via FTP nightly.

How to Abstract NCI-Specific Information

1. Search for the trial of interest. For instructions, refer to Searching for Trials in PA.
2. In the search results, click the NCI Trial Identifier link for that trial. The Trial Identification page appears.
3. On the **Trial Identification** page, check out the trial. For instructions, refer to Checking In and Checking Out Trials. (This checkout step is optional for Super Abstractors.)
4. On the **Administrative Data** menu, click **NCI Specific Information**. The NCI Specific Information page appears. It displays different fields according to the trial's Data Table 4 category (study source) and the criteria described in the matrix in Conditions for Sending Trial Information to ClinicalTrials.gov. The following factors determine which fields appear on this dialog box:
    - If the lead organization for the trial belongs to an organization family, the Program Code field is available. The Program Code field lists all program codes available for that organization family.
    - CTRP does not send Abbreviated trials in the batch files, and therefore does not display the option to indicate whether to send the trial.
    - For a Complete trial that has been sent to ClinicalTrials.gov in the batch files previously, CTRP does not display the option to indicate whether to send the trial in the future.
    - For a Complete, NCI-sponsored trial, CTRP displays the option to indicate whether to send the trial in the future and the Comments field. The default setting for this option depends on whether the trial has been sent to ClinicalTrials.gov previously:
        - For an original submission (which therefore has not been sent to ClinicalTrials.gov previously), the option to indicate whether to send the trial defaults to Yes, but CTRP displays the option to exclude the trial in the future.
        - For a trial that may have been updated and that had not been sent to ClinicalTrials.gov when submitted originally, it defaults to No, but CTRP displays the option to send the trial in the future.
5. On the **NCI Specific Information** page, in the various fields, specify the appropriate information. The following table describes the fields. An asterisk (*) indicates a required field.

Field Label	Description/Instructions
Reporting Data Set Method*	Specifies how CDUS accruals are submitted to CTEP. Select one of the following methods used for the principal investigator summary report: • **Abbreviated** - Requires minimal subset of data for reporting (for example, demographics) • **Complete** - Larger set of data (for example, includes outcomes) • **AE** (Adverse Events). Adverse events statistics are reported > This field does not reflect the trial category, even though it uses similar terminology.
Data Table 4 Funding Category	Select a trial type based on the role/responsibility/participation in the study. For information, refer to CTRP Trial Categories, Study Sources and https://cancercenters.cancer.gov/GrantsFunding/eData#dt4.
Data Table 4 Funding Sponsor /Source	To add a sponsor, click **Add Sponsor** and search for the name of the external sponsor or funding source as defined by the Data Table 4 report. (See Searching for Organizations.) > A trial can have multiple sponsors. The system ensures that you don't duplicate an existing sponsor. To delete an existing sponsor, click **Delete Sponsor**. You can not "undo" the deletion but you can add the sponsor back if necessary. Refer to https://cancercenters.cancer.gov/GrantsFunding/eData#dt4 for further information about specific Funding Sponsors.
Industrial?	For *Abbreviated* trials, indicate whether the trial is an Industrial trial, or other category, according to the matrix in Industrial Values. Because most *Abbreviated* trials are Industrial, the default value during trial registration is "YES". For Consortia trials, select one of the other values.

Program Code	The Program Code field lists all program codes available for the organization family of the lead organization. Select one or more program codes. The program codes are generally entered by the trial submitter. To view or modify a different family's program codes, refer to the Registration Site Administration chapter of the Registration User's Guide.
Send Trial Information to ClinicalTrials.gov?	For *Complete* trials, select one of the following to indicate whether to send the trial information to ClinicalTrials.gov in the automated nightly batch updates (via FTP): • **Yes**. Trial will be sent. • **No**. Trial will not be sent. If you select **Yes**, the CTRP system sends the information to ClinicalTrials.gov. If PRS indicates to the CTRP system that it processed the trial successfully, the CTRP system does not display this option in the future for this trial. For further information about this field, see Conditions for Sending Trial Information to ClinicalTrials.gov.
Comments	Enter a comment about your selection.
NCI Division /Department	Select the division or department that is managing the trial. | # | Value | Definition | |---|---|---| | 3 | CCR | Center for Cancer Research | | 6 | CIP | Cancer Imaging Program | | 1 | CTEP | Cancer Therapy Evaluation Program | | 4 | DCCPS | Division of Cancer Control and Population Sciences | | 7 | DCEG | Division of Cancer Epidemiology and Genetics | | 2 | DCP | Division of Cancer Prevention |
NCI Program	Select one or more relevant programs. | # | Value | Definition | |---|---|---| | 1 | BIQSFP | Trials maintained by the Biomarker, Imaging, and Quality of Life Studies Funding Program. | | 6 | ETCTN | Trials maintained by the Experimental Therapeutics Clinical Trials Network. | | 4 | NCORP | Trials maintained by the Community Oncology Research Program. | | 5 | NCTN | Trials maintained by the National Clinical Trials Network. | | 2 | SPORE | Trials maintained by the Specialized Programs of Research Excellence. | | 3 | Steering Committee | Trials maintained by leading cancer experts, community oncologists, biostatisticians, translational scientists, and advocates as well as NCI senior investigators. |

6. Optionally, to view the details of the Data Table 4 Funding Sponsor/Source (if already recorded), click the **Details** icon ().

Displaying Organization and Person Details

You can display the details of any organization or person, including their CTEP and PO IDs, that appears on abstraction pages by clicking the **Details** icon () located next to an organization or person name field.

7. To save the details you have abstracted, click **Save**.

For more information, refer to the following pages: