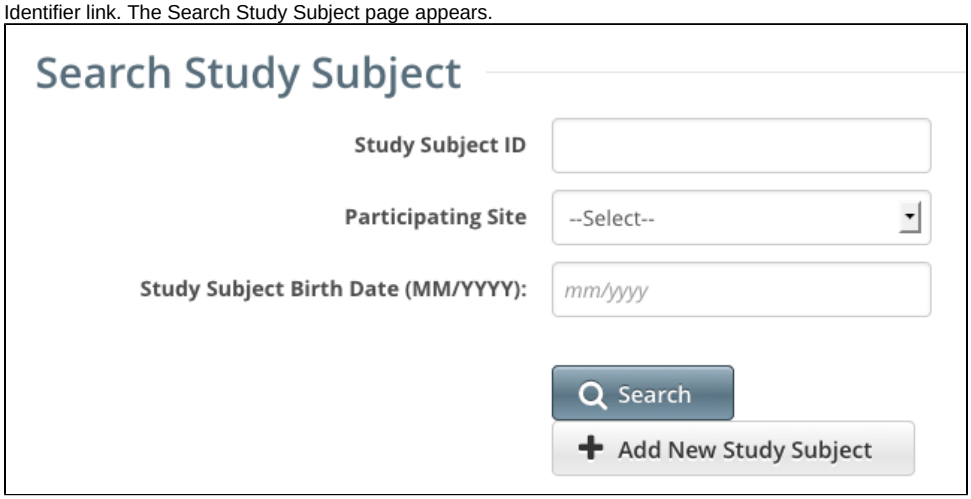
Adding Study Subjects - Include v4.4

You can add one or more study subject accrual records for any trial to which you have been granted access. [1] If necessary, refer to Requesting Permission to Submit Accrual Data.

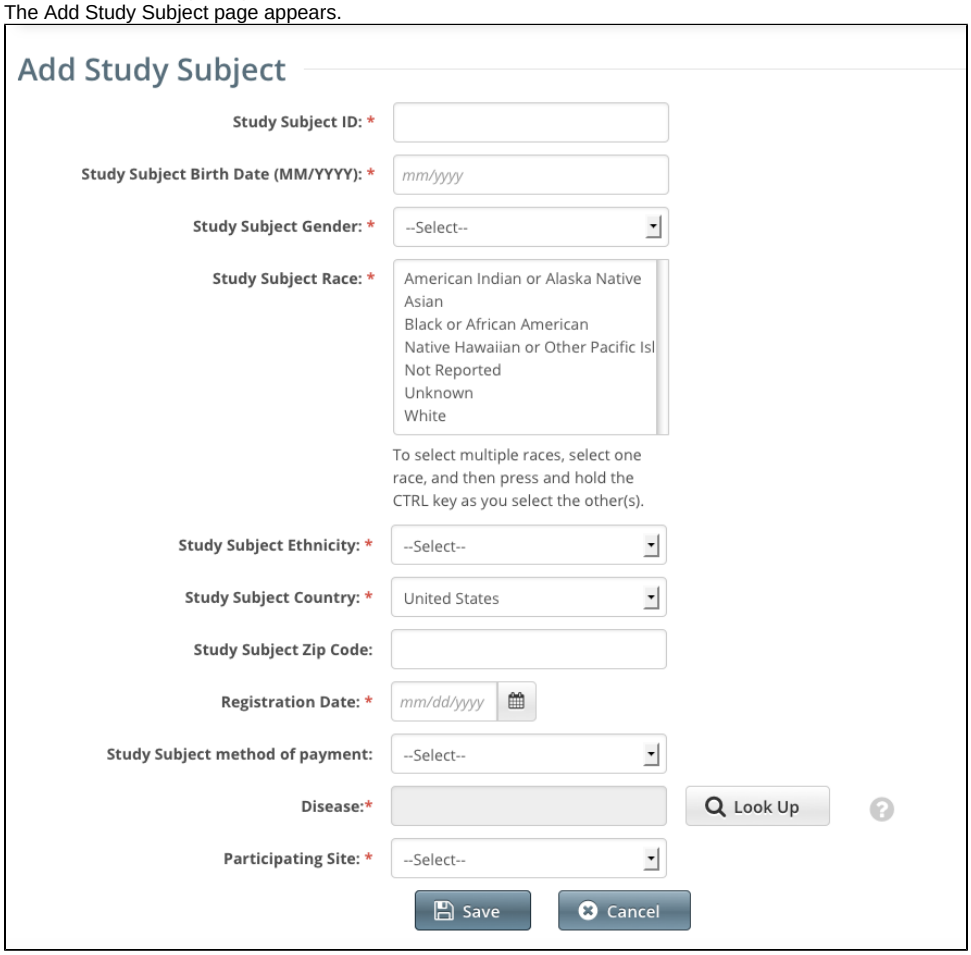
Study subject records include demographic data as well as the disease name.

How to Add Study Subject Records

1. Select the trial you want to work with by following instructions in Searching for and Selecting Your Trials, and clicking the corresponding NCI Trial Identifier link. The Search Study Subject page appears.



2. Click **Add New Study Subject**.
   The Add Study Subject page appears.



3. Enter the appropriate demographic information in the text fields and drop-down lists. The following table describes the fields. An asterisk (*) indicates a required field. For a list of valid values and formats for each field, refer to Accrual Data Elements for Complete Trials.

   Descriptions and instructions for study subject demographic data fields

Study Subject Information	Instruction/Description
Study Subject ID*	Enter the unique Patient ID as per the lead organization or the study site where the subject is registered.
Study Subject Birth Date*	Enter the subject's month and year of birth in the format **`MM/YYYY`** .
Study Subject Gender*	Select the subject's gender. If gender information is not available, select **Unknown**.
Study Subject Race*	Select one or more values for race. To select multiple races, select one race, and then press and hold the **CTRL**/**CMD** key as you select the other(s).
Study Subject Ethnicity*	Select a value for ethnicity.
Study Subject Country*	For non-U.S. residents only. This should be used when patient participation from foreign countries is involved. For patients from outside the U.S., enter the foreign country code. Leave blank if the patient is a U.S. resident. CTRP is using the International Standards Organization country codes. Note: Either Zip code (if U.S resident) or country code (if not U.S resident) is mandatory.
Study Subject Zip Code	Enter the study subject's zip code. This field is mandatory if the Study Subject Country is the U.S.
Registration Date*	Enter the date that the subject was registered for the trial.
Study Subject Method of Payment	For United States study subjects only, select the appropriate payment method.
Site*	Click **Look Up**, and follow the instructions in Selecting Sites for Study Subject Records Using ICD-O-3 Codes. Mandatory for ICD-O-3 trials unless you record a ICD-O-3 Disease Code. It's required to record both Topography and Morphology codes. Site codes are available at http://training.seer.cancer.gov/head-neck/abstract-code-stage/codes.html.
Disease*	Click **Look Up**, and follow the instructions in Selecting Diseases for Study Subject Records. Mandatory for ICD-9, SDC, ICD10 and ICD-O-3 trials. When using ICD-0-3, the disease code for Morphology must include both histology and behavior.
Participating Site*	Select the appropriate site from the drop-down list.

4. Click **Save**.
   The study subject record appears in the List of Study Subjects.

For *Complete* trials, lead organizations report all subjects accrued for the trial (both in the lead organization and in all participating sites). For *Abb reviated* trials, each participating site reports the number of its own accruals (accrual count) only.

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1. If your organization currently submits subject accrual information for studies to CTEP or DCP via the OPEN system, continue to report subject accrual information via OPEN. The NCI will manage the transfer of subject accrual data for OPEN trials internally. Otherwise, submit your organization's subject accrual data to CTRP.