Chapter 28: Special Studies

In SEER*DMS, "Special Studies" consist of user-defined criteria to determine the eligibility of incoming records for the purpose of rapid case ascertainment. The criteria specified for a Special Study are applied to records as they move through the workflow's auto-screening task. The criteria may define a record as "in the study", "out of the study", or "possible data for the study". In addition, you may use the SEER*DMS editor to manually assign records or patient sets to a special study.

Special study criteria are applied to incoming records as they move through the automatic screening task. A manual Review Special Studies task is generated if the record is identified as a "possible" match for the study. Instructions for completing this task are included in the *Manually Modifying Special Study Eligibility* section of this chapter.

Records are only screened for a special study if they move through auto-screening after the special study is defined. Patient Set data are not auto-screened for special study eligibility. External queries must be used to determine patient set eligibility and eligibility of records screened prior to a study's creation. Mass Change imports or ad hoc editing can be used to modify the special study fields which define whether a record or patient set is associated with one or more studies. The syntax for using Mass Change imports to modify special studies is provided on the Imports help page. Instructions for manually setting special study fields in records and patient sets are provided in the *Manually Modifying Special Study Eligibility* section of this chapter.

External queries must be used to extract or analyze data based on special study fields. Sample SQL related to special studies are available on the SEER*DMS Portal: *https://seer.cancer.gov/seerdms/portal/sql-tutorials/sql/special-studies*.

In this chapter, you'll learn about

- Defining a Special Study
- Deleting a Special Study
- Manually Modifying Special Study Eligibility

Defining a Special Study

Requires system permission: *study_add* or *study_edit*

To add a new Special Study or change the definition of an existing study:

1. Special Study selection criteria must be expressed in SQL statements. Write and test the SQL in an external tool (e.g., SQL Workbench) prior to adding the criteria to a special study.
2. Select **Manage > Special Studies**. All studies will be shown in order of Study ID.
3. To create a new study, select **Add** from the **Actions** menu (this will only be shown if you have the *study_add* permission). To modify an existing study, click the study's ID. You may search for a study using the filters for Study ID, Name, Description and Status.
4. Enter a **Study ID** consisting of 2-20 alphanumeric characters (the underscore character is also permitted). Study IDs are case sensitive; all letters are automatically converted to lower case when the study is created or modified.
5. Enter a **Study Name** consisting of 1-50 characters of any type.
6. You may enter a longer description of the study in the **Description** field.
7. Use the **Active** checkbox to set the study's status field to the appropriate value. Check this box for active studies. Uncheck this box to change the status to inactive. A record will not be screened for eligibility for inactive special studies; records and Patient Sets cannot be

manually added to inactive special studies. External processes could be used to determine eligibility for inactive special studies. Mass Change Imports could be used to set special study flags in inactive studies.

8. If you are creating a new study, you must click **Save** at this point. The study will now be included in the list of studies in the Special Study Manager and in the Special Study section of the record and Patient Set editors. Instructions for adding a record or Patient Set to a special study are provided in the *Manually Modifying Special Study Eligibility* section of this chapter.
9. If you will not be using the SEER*DMS auto-screener to add records to the study, click **Cancel** to exit.
10. If records will be screened for the study as they enter the workflow, define the auto-screening criteria. If you are creating a new study, click **Add Criteria**. If you are modifying an existing study, you may add, edit, or delete criteria.
    a. Enter a **Description** of the selection criteria.
    b. Set the Inclusion level. If a record is screened and meets the criteria, the record will be added to the special study with this inclusion setting.
        i. **In** – Records meeting the criteria fulfill eligibility requirements for the study.
        ii. **Possible** – Records meeting the criteria should be reviewed by registry staff to determine study eligibility.
    c. Select a value for **Manual Screening Required**. If this field is set to yes then a Review Special Studies task will be created for each record that matches the criteria.
    d. Enter text into the **Criteria** text box that completes the SQL statement which begins with the text in Query. Special study screening is only available for record data.
    e. Click **Validate** to check for syntax errors in the SQL statement. Validate only checks SQL syntax and does not perform reasonableness checks. As stated before, the SQL must be written and tested in an external tool prior to defining the study in SEER*DMS.
    f. Click **Counts** to determine the number of records in the database which currently meet this criteria. This count should match the value that you calculated when testing the SQL. The count includes records that have already been screened. SEER*DMS automatically screens for special study eligibility during the screening worklist task. If you wish to include records that were previously screened, use a Mass Change import or ad hoc editing to set the special study fields for the records.
11. Click **Add** or **Update** to save the criteria. From this point forward, the new criteria will be applied to records as they move through the screening task in the workflow. You may use external queries to extract or analyze data based on the study inclusion flags
12. Click **Save** to save all changes to the Special Study.

Deleting a Special Study

Requires system permission: *study_delete*

If you delete a special study, all traces of the study are removed from the system. This includes the criteria defined in the study and indicators in records and patient sets related to the study. To re-create the study, you would need to add the study in the manager. You would then need to run external queries to identify data for the study. Finally, you would need to use a Mass Change import or ad hoc editing to set the special study fields for the records or patient sets.

To delete a Special Study:

1. Select **Manage > Special Studies**. All studies will be shown in order of Study ID.
2. You may search for a study using the filters for Study ID, Name, Description and Status.
3. Click the **ID** of the study to be deleted.
4. Review the study to be certain that you are deleting the appropriate study. Pay particular attention to the Data Summary shown in the upper right corner. As discussed above, several steps would need to be taken to redefine a study which is already populated with records or patient sets.
5. To proceed, click **Delete**.
6. Click **OK** to confirm.

Manually Modifying Special Study Eligibility

Requires system permission: (*study_pat_edit* and *pat_edit*) or (*study_rec_edit* and *rec_edit*)

A record is screened for reportability and special study eligibility during the automatic screening task. The primary objective of the auto-screening task is to set the reportability flag; the review of special study eligibility is a secondary process that never alters the route of the record in the workflow. It is possible that two manual tasks will be created after auto-screening: the primary workflow task (screening or match-consolidate, e.g.) and a secondary task to review special study eligibility. The Review Special Studies task only allows you to set special study eligibility; changes to other data fields must be made in another workflow task or in an ad hoc editing session.

In addition, you may add or remove data from a special study using controls within the SEER*DMS record and patient set editors. If an unlinked record is flagged for a special study and the record is subsequently linked to a patient set, registry policy dictates whether the person consolidating the data should manually set the special study indicator in the patient set.

To indicate whether data should be included in (or excluded from) a special study:

1. Open the record or patient set.
   a. If you are completing a Review Special Study task, open the task.
   b. If you need to change the special study status of a record or patient set that is not in the workflow, use the Data Search or Patient Lookup to find and open the data in the editor (instructions for searching the database are provided in *Chapter 20: Searching for Records and Patients*).
2. Review the record or patient set data. If this is a Review Special Study task, the data will be displayed in read-only mode and you will only be able to modify special studies.
3. Click the **SS** link in the navigation box on the left side of the screen.
4. Select the study to add or modify:
   a. To add the data to a study, click **Add**. Select the **Study ID** from the drop-down list. Inactive studies will be listed but cannot be selected.
   b. To modify settings for a study, click the **Edit** link in the Action column for the study. To edit the special status of a linked record, you must open the record for editing (select **Edit Record** from that record's menu).
5. Based on registry policies, set the **Inclusion** status to:
   a. **In** – The record fulfills eligibility requirements for the study.
   b. **Out** - The record meets screening criteria for the study, but upon review, you determined that the record is ineligible. For example, the physician did not give approval for the patient's inclusion, or the patient declined to participate.

c. **Possible** – You are unable to make a definite determination of the record's eligibility at this time.

d. If the screening algorithm incorrectly identified a record or patient set as a candidate for a study, click **Delete** and inform registry management. Registry policy dictates when delete is used versus setting the status to out. A status of out can be used to indicate that the record was reviewed.

6. If you know of a study-specific ID for this record, enter the value in **Participant ID**.
7. You may document your changes by adding a comment.
8. Click **Add** or **Update** to complete the study information.
9. The changes made to special studies are not saved until the full record or patient set is saved. To save your changes to special studies and other fields:

   a. Click **Save**.

   b. If you would like to save these changes but continue editing, click the **Save** button at the bottom of the Review Changes page.

   c. If you would like to exit the editor, click **Save & Exit**.