

## Enrolling a Patient in StudyManager

1. Select the patient to enroll by using the *Patient List* filters.
2. Once the patient is selected, click **Add Patient to Study**. The *Add Patient to Study* box displays.

3. Select a **study** from the drop down list.
4. **Select investigator** from the drop down list.
5. Select **coordinator** from the drop down list.
6. Select a **site** from the drop down list. This is the site the study patient will be associated with, when enrolled in the study. This will be different from the site, “Children’s Hospital” which is associated to the general patient record on the *Patients* screen.
7. Select **hospital** from the drop down list. This should be “Children’s Hospital” unless tracking patients enrolled at another hospital participating in the study.

The screenshot shows a dialog box titled "Add patient to study". It contains the following fields and options:

- Five dropdown menus labeled "Select study:", "Select investigator:", "Select coordinator:", "Select site:", and "Select hospital:".
- An "Alias:" text input field containing the text "CCV".
- A section titled "Patient's initial status:" with four radio button options: "Pre-Screening", "Screening", "Randomized", and "On Study".
- At the bottom right, there are two buttons: "Submit" and "Cancel".

8. **NCI Reporting Studies only** – *Disease Site*. If the study is designated as an “NCI Reporting Study,” select the disease site that the patient will accrue towards on the NCI Summary 3 report.
9. **Multi-Arm studies only** – *Select arm*. If the study the patient is enrolled to is designated as a “Multi-Arm” study, specify the arm to which the patient was enrolled.
10. By default, the patient’s initials are used for the **alias**. Input another alias if desired. If two patients on the same study have the same alias, one must be changed. One way this can be done is by adding a “2” to the end of the alias.
11. Select an **initial status** for the patient. All study patients are assigned a current status when enrolled in studies, i.e. screening, randomized, dropped, failed. This status may be changed via *Patient Visits*, but an initial status must be assigned when adding a patient to a study:

- **Pre-Screening** –Use this status with patients who are not yet “screening,” but need to be tracked as “pre-screening.”

*Note: This is optional as only consented patients are required to be entered.*

- **Screening** – Use this status if the patient is to be considered a “screening” patient in the study at the time they are entered in StudyManager.
  - **Randomized** – Use this status if the patient is randomized to the study.
  - **On Study** – Use this status in lieu of randomized, if the study is not a randomized study.
12. If “Screening,” “Randomized,” or “On Study” is selected, Screening Date and Screening Number must be entered. These dates and numbers are required. Screening Number is assigned by the user, and must be unique for each patient in the study.
  13. If “Randomized” is selected, a Screening Date and Screening Number, as well as a Randomization Date and Randomization Number must be entered. These dates and numbers are required. These dates and numbers are assigned by the user, and must be unique for each patient in the study.
  14. Click **Submit** when finished. Click **Cancel** to exit the screen without saving.

Once a patient is added to the study, the *Patient Visits* screen displays on the right hand side of the screen. From here, visits can be added or edited and patient status can be changed to reflect their progress through the study.