Northern Light Health

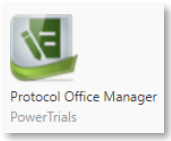
From the Office of Clinical Informatics

PowerTrials - Protocol Office Manager
Creating a Protocol

April 26, 2021

PowerTrials is a Cerner application that is used to support the management and patient enrollment into research studies. Protocol Office Manager is one of two applications in the suite of PowerTrials applications that is used to create and manage protocols.

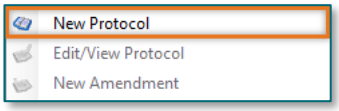
Creating a Protocol



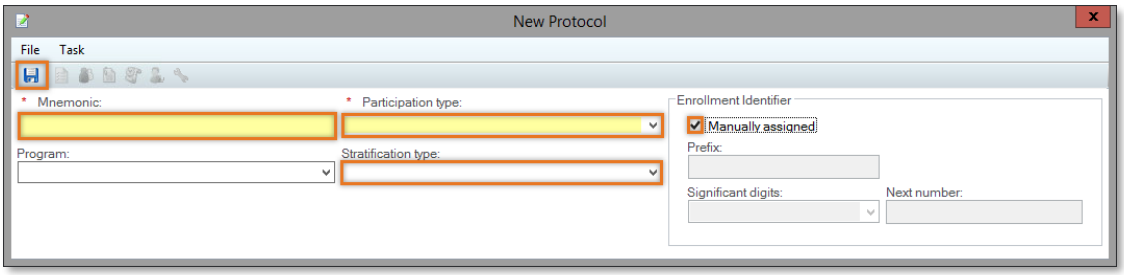
STEP 1: Log into **Protocol Office Manager**.

STEP 2: From the protocol tree, select an **Initiating Service**.

STEP 3: Right-click the folder and select **New Protocol**.



- The **New Protocol** dialog box opens. You will be required to fill out all the required yellow fields.



STEP 4: Enter a name of the protocol in the **Mnemonic** box. This is a short name of the protocol.

STEP 5: Select the **Participation Type**. This is the type of study being conducted.

- The **New Protocol** dialog box expands to include data boxes that are specific to the participation type you select.

STEP 6: Check the **Manually Assigned** box in the Enrollment Identifier group box to assign the enrollment identifier manually when patients are enrolled.

STEP 7: In the **Stratification Type** list, select the appropriate type for the study.

- This field indicates if the study has arms. **It is not in yellow, but it is required.**

STEP 8: Click the **Save** icon from the toolbar. It will indicate your protocol has been created.

IMPORTANT: When building out a new protocol, you won't be able to fill out your strata information until you Save the protocol.

STEP 9: Click the **Amendment Info** button.

STEP 10: **Amendment:** Area to place the longer title of the study.

STEP 11: **Accrual:** Enter information about the target accrual for the protocol.

- No Target: No specific number of patients to enroll.
- Estimate Only: An estimation on the number of patients that will be enrolled.
- Limited to Target: Once the protocol reaches the number of patients listed it will not allow you to enroll any more patients to the study.

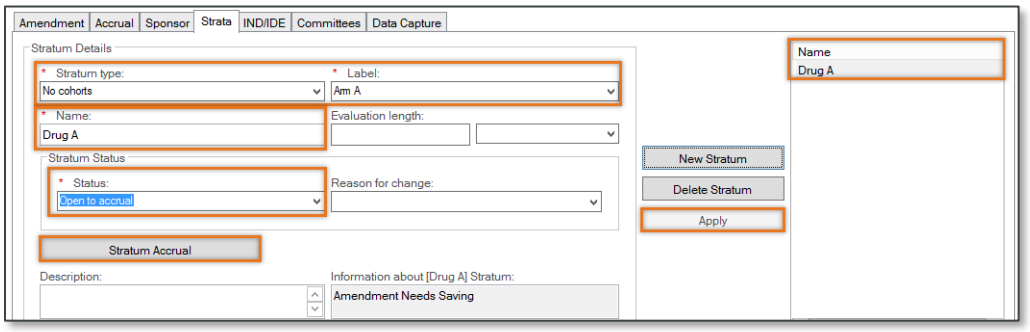
STEP 12: Click the **Strata** tab, then click the **New Stratum** button.

- When you create the arm, you will click **New Stratum** and then fill out all the yellow fields.

NOTE: **Only required if you indicated there are arms to your study. Houses the information about the different arms of the study.**

STEP 13: Complete the required **Stratum type, Label, Name, and Status** fields.

- **Stratum type**:
  - **No Cohorts** = the study has only arms (i.e. Drug A, Placebo). This is the most commonly used option.
  - **Multiple Cohorts can Accrue Simultaneously** = the arms for the study have sub-arms. Meaning Arm A would have a "child" arm "Arm A 1.0 and Arm A 2.0". These cohorts (or sub-arms) would be able to accrue patients at the same time.
  - **One cohort can accrue** = the arm has sub arms; however, only one of them can enroll patients at a time.

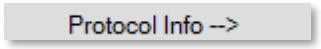


- **Label**: As the studies fill out the stratum information, they will select one Label per protocol. A protocol can only have one Arm A, one Arm B, etc.
- **Name:** Enter the name of the arm.
- In the **Status** list drop down list, select **Open to accrual.**

NOTE: **Once you have filled out the required fields you MUST click the Stratum Accrual button and indicate how many patients will be on this arm of the study.**

- Then click **Apply.**

STEP 14: Click the **Protocol Info** button.

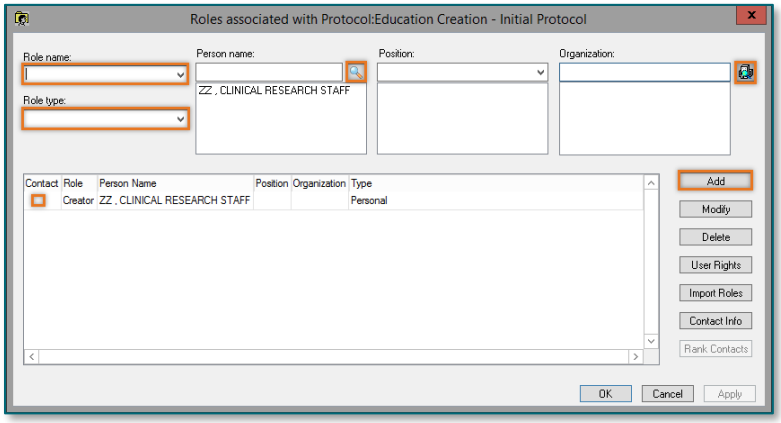


- In the **Study Type** list, select the appropriate study type from the list.
- Once you have completed filling out the tabs, click the **Save** icon from the toolbar.

Assigning Roles

In order to open the study to accrual you must have: **Principal Investigator, Creator**, and **Coordinating Institution**. The **Creator** of the study will be defaulted.

STEP 1: On the toolbar in the New Protocol window, select the **Roles** icon.



STEP 2: Enter the information for the **Coordinating Institution:**

- **Role Name:** Coordinating Institution
- **Role Type:** Organizational.
- **Organization:** Click the building icon to search for the name of your organization.
- Click **Add.**

STEP 3: Enter the information for the **Principal Investigator:**

- **Role Name:** Principal Investigator.
- **Role Type:** Personal.
- **Person Name:** Use the search icon to search for the person to be assigned this role.
- Click **Add.**

NOTE: **To identify contacts for a study, check the contact box next to the members of the study team listed.**

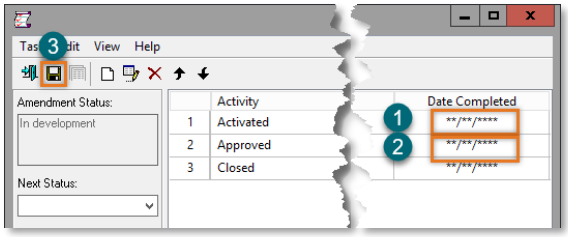
STEP 4: Enter the information for the **Study Coordinator:**

- **Role Name:** Study Coordinator.
- **Role Type:** Personal.
- **Person Name:** Use the search icon to search for the person to be assigned this role.
- Click **Add.**

STEP 5: Once all roles have been associated, click **Apply** and **OK** to close the Role window.

Milestones

Information entered about the milestones for the study will be done here. In order to open your study to accrual you must indicate the dates for **Activate** and **Approve**.

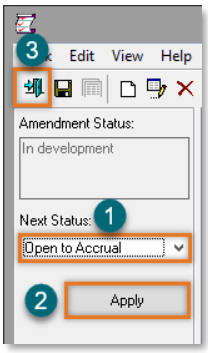


STEP 1: Select the **Milestone** icon on the toolbar.

STEP 2: Select **Protocol Default Milestone** you selected earlier when creating the protocol, then click **OK.**

STEP 3: Enter the dates for the **Activate** and **Approve** Milestones.

STEP 4: Click the **Activate** date field and select the appropriate activate date.



STEP 5: Select the **Approve** date field and use the drop-down arrow to the calendar to select appropriate approved date.

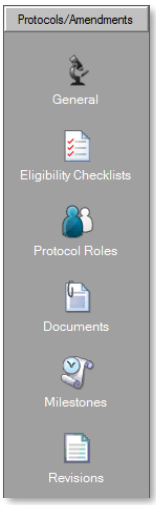
STEP 6: Click **Save.**

STEP 7: In the **Next Status** list, select **Open to Accrual**, then click **Apply.**

STEP 8: Click **Exit** to exit the Milestone tool.

STEP 9: In the top toolbar of the window, click **File** and select **Exit** to close the protocol.

STEP 10: Ensure the **Mnemonic** is selected in the protocol tree and review and verify the following components in the Protocols/Amendments navigator pane.



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