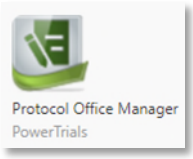
From the Office of Health Informatics

PowerTrials – Protocol Office Manager
Creating a Protocol

April 16, 2025

PowerTrials is a Oracle Health (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.

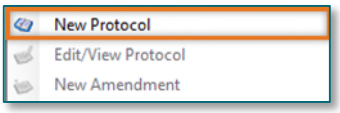
Creating a Protocol



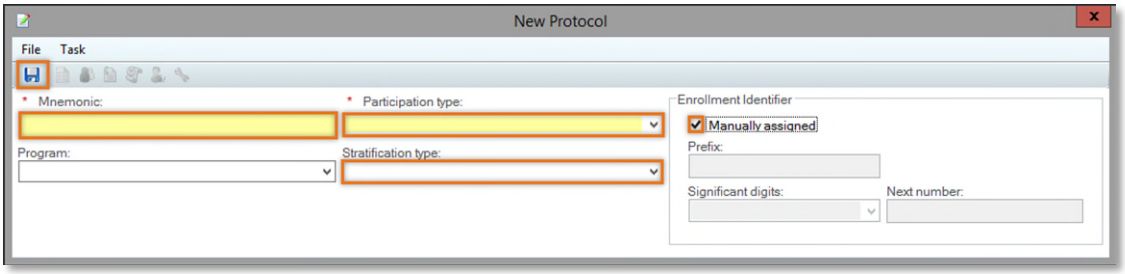
STEP 1: Log into **Protocol Office Manager (POM)**.

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. 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 selected.

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

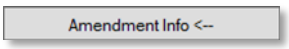
STEP 7: In the **Stratification Type** list, select the appropriate type for the study.

- 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. A small window displays indicating the protocol has been created.

IMPORTANT: When building out a new protocol, strata information cannot be filled out until the protocol is saved.

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

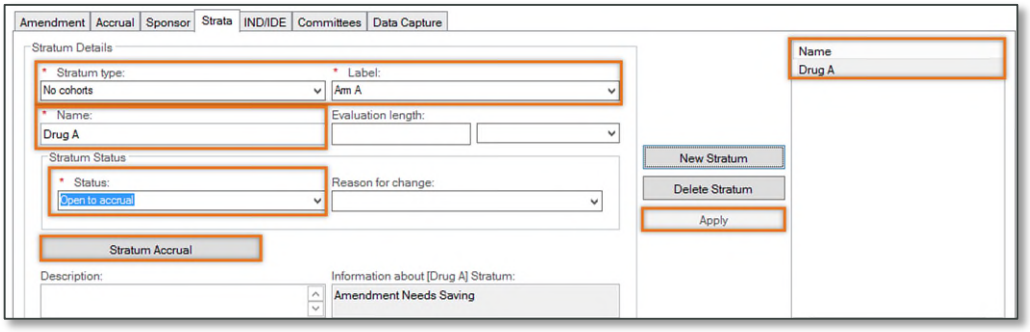


STEP 10: Review each tab and complete required fields and any fields appropriate for the protocol.

- **Amendment tab:** Area to place the longer title of the study.
- **Accrual tab:** 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.
- **Sponsor tab**: Enter applicable sponsor information for the protocol.
- **Strata tab**: Click the **New Stratum** button.
  - When creating the arm, click **New Stratum** and then fill out all the yellow fields.

NOTE: **Creating Stratum is only required if it is indicated there are arms to the study. This is where the information about the different arms of the study is entered.**

- 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 (i.e., 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, one Label is selected 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.**

▪ Then click **Apply.**

NOTE: **Once the required fields are filled out, the Stratum Accrual button must be clicked and indicate how many patients will be on this arm of the study.**

- **IND/IDE tab:** enter IND/IDE information part of the protocol.

STEP 11: Click the **Protocol Info** button.

▪ In the **Study Type** list, select the appropriate study type from the list.

STEP 12: When complete, click the **Save** icon from the toolbar.

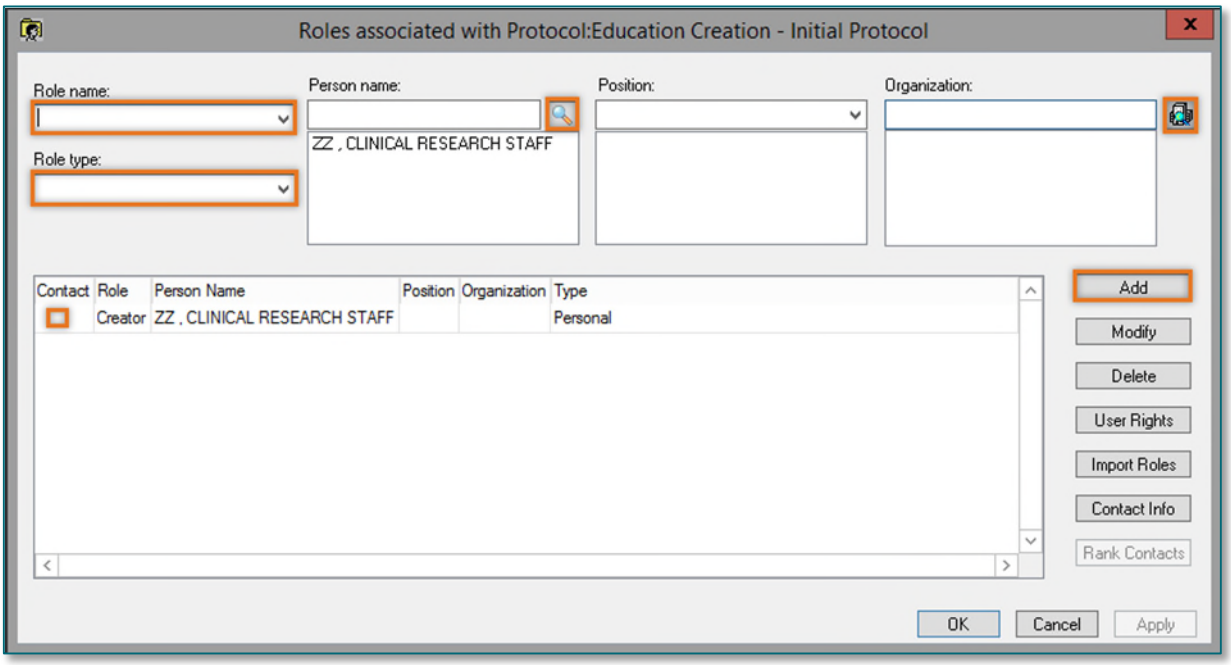
Assigning Roles

In order to open the study to accrual, the protocol must have the following roles: **Principal Investigator**, **Creator**, and **Coordinating Institution**. By default, whomever created the protocol is listed as the Creator.

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 organization name.
▪ 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 designate people as the protocol contacts, check the box in the Contacts column next to the members of the study team.**

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: Add other roles applicable to the protocol following the same steps used for the roles above.

STEP 6: Once all roles have been associated, click **Apply** and **OK** to close the Role window.

Milestones

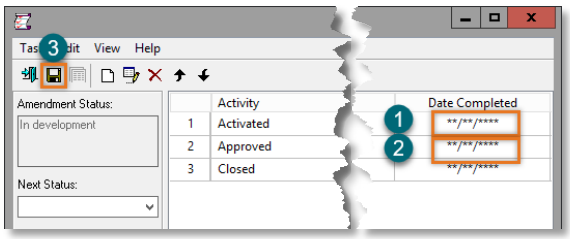
Milestone information for the study is entered here. In order to open the study to accrual, the **Activate** and **Approve** fields must be filled in.

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

STEP 2: The Default Milestone dialogue box displays. Select the option chosen earlier when creating the protocol, then click **OK**.

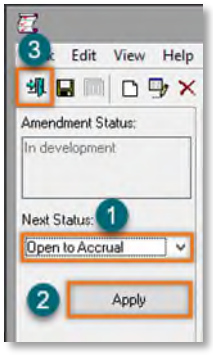
STEP 3: Enter the **Activate** and **Approve** dates.

- Click the **Activate** date field and select the appropriate activate date.
- Select the **Approve** date field and use the dropdown arrow to the calendar to select appropriate approved date.



STEP 4: Click **Save**

STEP 5: In the **Next Status** field, select **Open to Accrual**, then click **Apply**.



STEP 6: Click **Exit** to exit the Milestone tool.

STEP 7: In the top toolbar of the window, click **File** and select **Exit** to close the protocol.

STEP 8: Ensure the **Mnemonic** is selected in the protocol tree and review and verify the following components in the **Protocols/Amendments** navigator pane.

- General
- Protocol Roles
- Documents
- Milestones
- Revisions