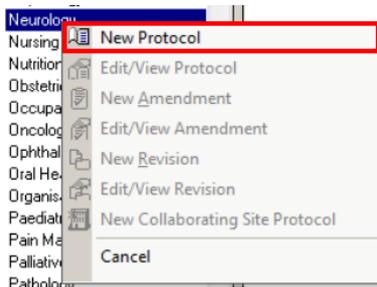


PowerTrials: POM – create new protocol

Quick reference guide

Protocol Office Manager (POM) is used to create and manage research studies within the *PowerTrials* solution.

1. Within *POM*, right click on the *Initiating Service* folder that the protocol will be listed under.



2. Click *New Protocol*.

The *New Protocol* window will open.



3. Complete the details for your new research study.
 - a. *Mnemonic*: Unique name of that protocol (Please follow your facility naming conventions)
 - b. *Program*: Division initiating the study
 - c. *Participation Type*: Documents the participation type for the research study.
 - d. *Stratification Type*: Stratified/Non-Stratified
 - e. *Enrollment Identifier*: This checkbox is used to either manually assign enrolment identifiers or automatically assign the identifier to patients during the enrolment process

Additional *Protocol Information* will become available in the window once the above section has been completed.

4. Complete the various tabs and fields under *Protocol Information*:

- a. *Initiating Service*: Defaults to the folder selected in Step 1.
- b. *Study Type*: Therapeutic/Non-Therapeutic
- c. *Phase*: Select the appropriate phase of the study.
- d. *Contributing departments*: Select specific departments that are also involved with the running of the study
- e. *Regulatory reporting types*: Governance and Ethics committees (RGO and HREC)

5. Click *Save*.

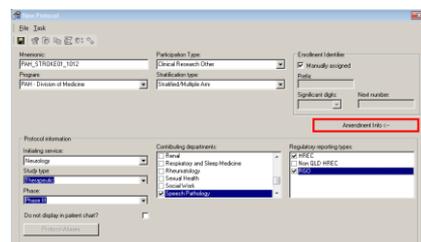
The below prompt window will appear confirming the new protocol has been created.

6. Click *OK*.



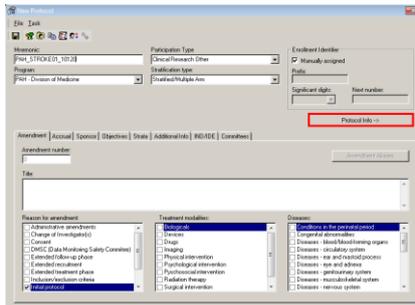
The *Amendment Info* will display with the *Amendment* tab open.

7. To alternate between *Amendment Info* and *Protocol Info*, click the respective button.



Or





8. Within the *Amendment* tab, complete the details below:

- a. *Title*: This is to be the full name of the study. Include the HREC and RGO numbers for your study.
- b. *Reason for amendment*: Initial protocol will be selected for a newly created protocol
- c. *Treatment modalities*: Drug, Device, Surgical intervention etc
- d. *Diseases*: What area of disease does the study focus on

9. Click *Save*.

To define the protocol parameters, the other tab within *Amendment Info* will need to be completed. Please refer to the *POM 3 Define Protocol Parameters QRG*.

