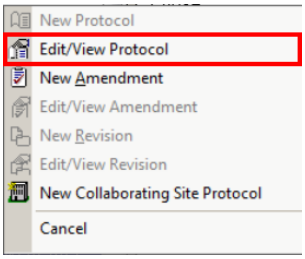
PowerTrials: POM – Define Protocol Parameters

Quick reference guide

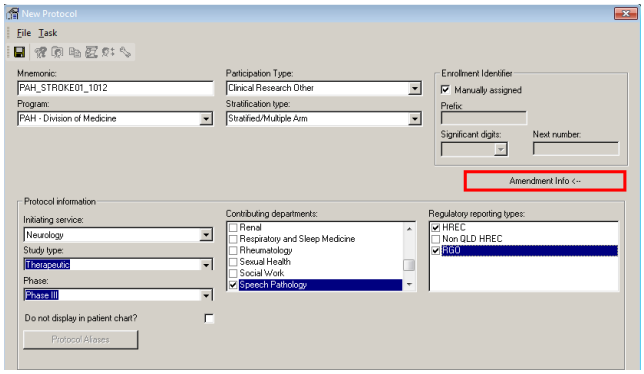
Once a protocol is created within *POM*, the protocol parameters will need to be defined within the *Amendment Info* section. Refer to *PowerTrials: POM – Create New Protocol QRG* if the protocol has not yet been created.

1. Within *POM*, right click on the protocol under the *Initiating Service* Folder.
2. Select *Edit/View Protocol*.

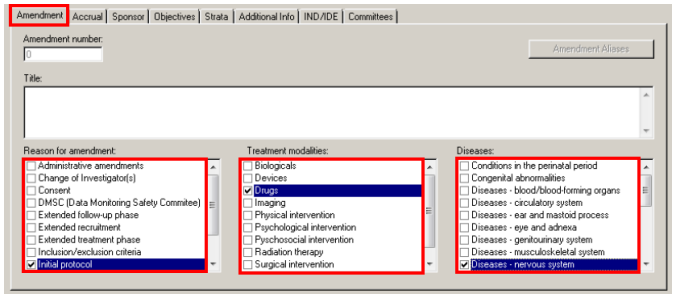


The *Edit Protocol* window will open.

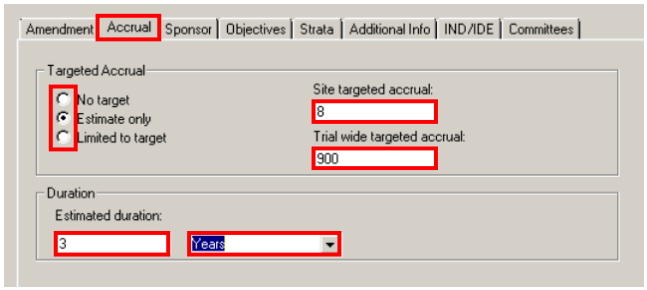
3. Click the *Amendment Info* button, if required.



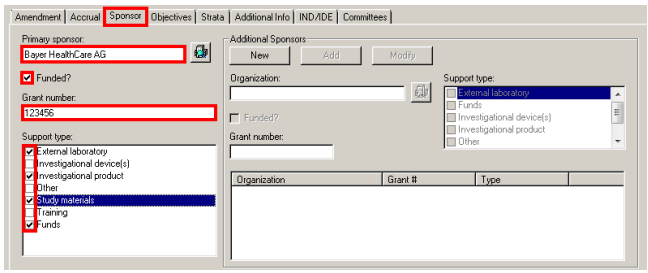
4. Complete the *Amendment* tab if not yet done:
   - *Title*: This is to be the full name of the study.
   - *Reason for amendment*: Initial protocol will be selected for a newly created protocol
   - *Treatment modalities*: Select the appropriate treatment method being used in the study
   - *Diseases*: This will be the primary system in which the study is being conducted for, e.g. Neurology will be Diseases – Nervous System.



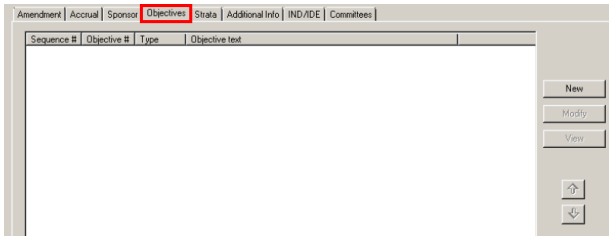
5. Click the *Accrual* tab and complete information required:
   - *Targeted Accrual*: Select the appropriate option if there is Targeted Accrual. If *Limited to Target* is selected, the system will not allow the user to enrol more than the number stated.
   - *Site targeted accrual*: Input target number of patients for this site
   - *Trial wide targeted accrual*: If the study is a multi-facility trial, input the trial-wide target for patient accrual
   - *Duration*: Record the estimated duration of the research study



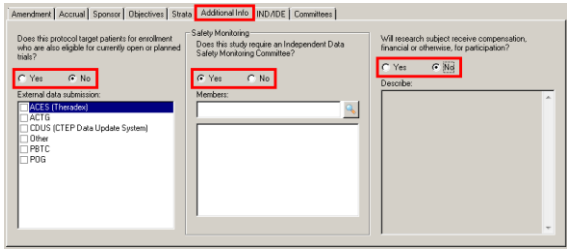
6. Click the *Sponsor* tab and complete information required:
   - *Primary sponsor*: Search for and input the primary sponsor
     - If a sponsor is not available in the list, a job will need to logged to have them added.
   - *Funded?*: Tick checkbox if study is funded
   - *Grant number:* Type Grant number, if applicable.
   - *Support type*: Tick the elements the sponsor will provide
   - *Additional Sponsors*: Can be added by clicking New and completing the same information.



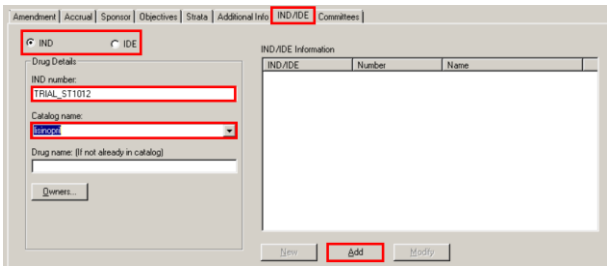
7. Click the *Objectives* tab and complete information, if required.
   - Click *New*
   - Enter *Objective Number*
   - Select *Type*
   - Type *Objective Statement*
   - Click *OK*



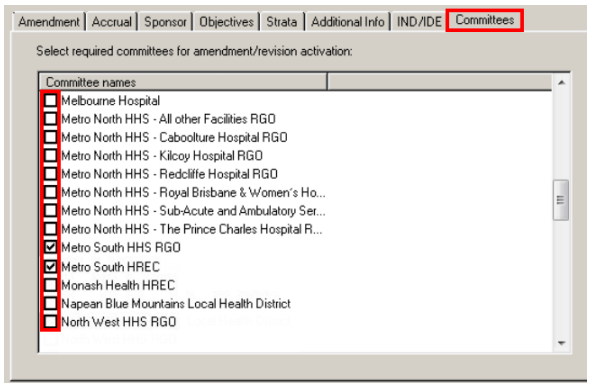
8. Click the *Strata* tab and complete Arm/Cohort information if applicable. Please refer to the *PowerTrials: POM – Arm/Cohort Information QRG.*
9. Click the *Additional Info* tab and answer the questions displayed:



10. Click the *IND/IDE* tab and complete information required:
    - Click *New*
    - Click the appropriate button - *IND/IDE:* Aust. CTN/CTX
        - *IND*: IND Number, Catalog Name, Drug Name
        - *IDE*: IDE Number, Device Name and IDE Type
    - Click *Add*



11. Click the *Committees* tab and tick the relevant committee/s. Protocols will need to enter in both the Ethics and Governance Committees unless an exemption has been granted.



12. Click *Save*.