Our Digital Future
IMAGINE WHAT'S POSSIBLE...

ieMR Advanced

PowerTrials: POM – define protocol strata and cohorts

Quick reference guide

Once a protocol is created within *POM*, the protocol parameters need to be defined within the *Amendment Info* section. Refer to *POM 3 Define Protocol Parameters QRG* for configuring the Amendment, Accrual, Sponsor, Objectives, IND/IDE and Committees properties for a protocol or amendment.

This QRG specifically explains how to define different strata and cohorts that may be used in a clinical trial or research project.

1. Within *POM*, right click on the relevant protocol or amendment under the *Initiating Service Folder*.

2. Select *Edit/View Protocol*.
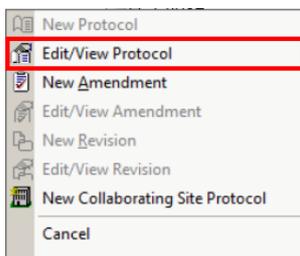
The *Edit Protocol* window will open.

3. Click the *Strata* tab to access the Strata configuration settings.

4. To add a new stratum, click the *New Stratum* button and complete information as required:

   a. *Stratum type*: Select the appropriate type to reflect how cohorts will be recruited in the study;

   b. *Label*: Select which arm (A to K) of the protocol this stratum will refer to;

   c. *Name*: Enter a name for the stratum that refers to how it is unique from any other stratum in this protocol;

   d. *Evaluation length*: Enter the time used for evaluation – time can listed be in Days, Months or Years.
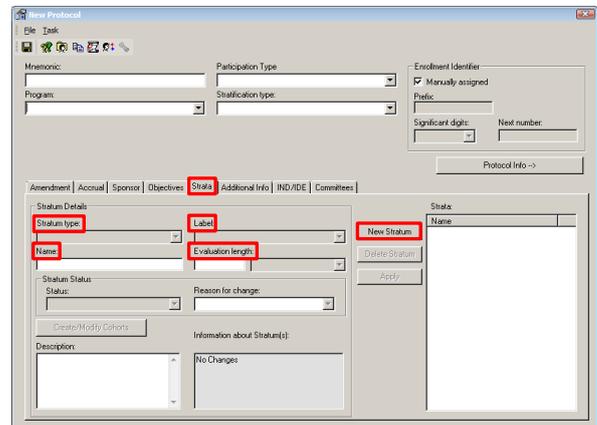
Once you have entered the Stratum Details, the greyed out *Create/Modify Cohorts* button will change to the *Cohort Information* button and will no longer be greyed out.

5. Click on the *Cohort Information* button to enter information for each cohort that will be used in this stratum and complete information as required:

   a. *Number of enrollees*: How many patients can be enrolled into the protocol;

   b. *Effective Dates*: Enter relevant dates in the *From* and *To* date fields. Dates can be entered by typing them in dd-mmm-yyyy format (e.g. 04-Oct-2017) or using the calendar that can be accessed by clicking the down arrow button;

   c. *Cohort*: Enter a name for the cohort;

   d. *Status*: Use the drop-down menu to choose the cohort status – in most cases, select *open to accrual;*

   e. *Cohort description*: Enter a brief description for the cohort;

Queensland Government

Once you have entered the Cohort Details, the *Apply* button will no longer be greyed out;

f. Click *Apply* to create the cohort.

6. Repeat this for any more cohorts you need to create for the stratum.

7. Click *Close* to return to the Strata Information settings.

8. Enter a description for the stratum.

9. Click *Apply* to create the stratum.

10. Repeat steps 4 to 9 above to create any other strata that are required for the protocol.

11. Click the *Save* icon to save the strata and associated cohorts to the protocol.

12. To configure any other protocol / amendment parameters, refer to *POM 3 Define Protocol Parameters QRG*.

13. To exit the *Edit Amendment* window, select *File* from the menu, then the *Exit* option.