Sample Size

This section sets up the number of patients and the cohort size for the trial:

Cohort Size: The number of patients given the same dose and that can be accrued without knowing the outcomes. The size can vary from 1 to 4 patients.

Number of cohort: The number of cohort desired. The maximum total number of patients (the product of cohort size and number of cohort) can be 200. Thus, the sample size for the design will be a multiple of the cohort size.

The last box in this group allows a specification of the maximum accumulative number of patients that can be assigned to a dose. The rationale is that if this number has been reached, it suggests that the dose finding may have converged, and thus the trial can be stopped and select the MTD early. The objective of this early selection rule is to save the sample size and shorten the trial duration. We recommend a value >= 12. A value greater than the sample size effectively disables this early selection rule.