

## Doses & Sample Size

This section sets up the dose structure and sample size related parameters for the trial:

**Number of doses** - Specifies the total number of doses for the Drug. A minimum of two and a maximum of 20 doses are allowed.

**Starting dose level**- Specifies the first dose level for the trial and can range from 1 to the maximum number of doses.

**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.

**"Stop trial if number of patients assigned to single dose reaches  $m$  and the decision is to stay"** checked allows stopping the trial early if  $m$  patients have been treated at the current dose and the decision for the next cohort of patients is to stay at the same dose. The rationale for this early stopping rule is that if a relatively large number of patients have been treated at a dose, it suggests that the dose finding may have converged, and thus the trial can be stopped and select the MTD early. This rule reduces the sample size and shortens the trial duration. We recommend  $m \geq 12$ . To disable this early stopping rule, simply uncheck the box.