3 + 3 design

The 3 + 3 design is a common approach in phase 1 trials. It involves sequentially enrolling small groups of participants, typically three participants per dose level, with a predefined dose escalation plan. If no dose-limiting toxicities (DLTs) occur in a group, the next group is enrolled at a higher dose. If a DLT occurs in one or more participants, the previous dose level is considered the maximum tolerated dose (MTD).

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Last update: 2024/06/07 02:57

