

Modify the decision from de-escalation to stay when observing 1 DLT out of 3 patients

When observing 1 DLT out of 3 patients and the target DLT rate is between 0.25 and 0.279, the optimal decision is to de-escalate the dose. This is because, given 1 DLT out of 3 patients, the likelihood of overdosing (i.e., 0.35) is higher than the likelihood of proper dosing (i.e., 0.25). However, due to the long history of using the conventional 3+3 design, when observing 1 DLT out of 3 patients, staying at the current dose is a widely accepted practice. This option allows users to change the BOIN decision from de-escalation to staying, aligning it with that practice. We found that making this modification, or not, has a very minor impact on the operating characteristics of the BOIN design.