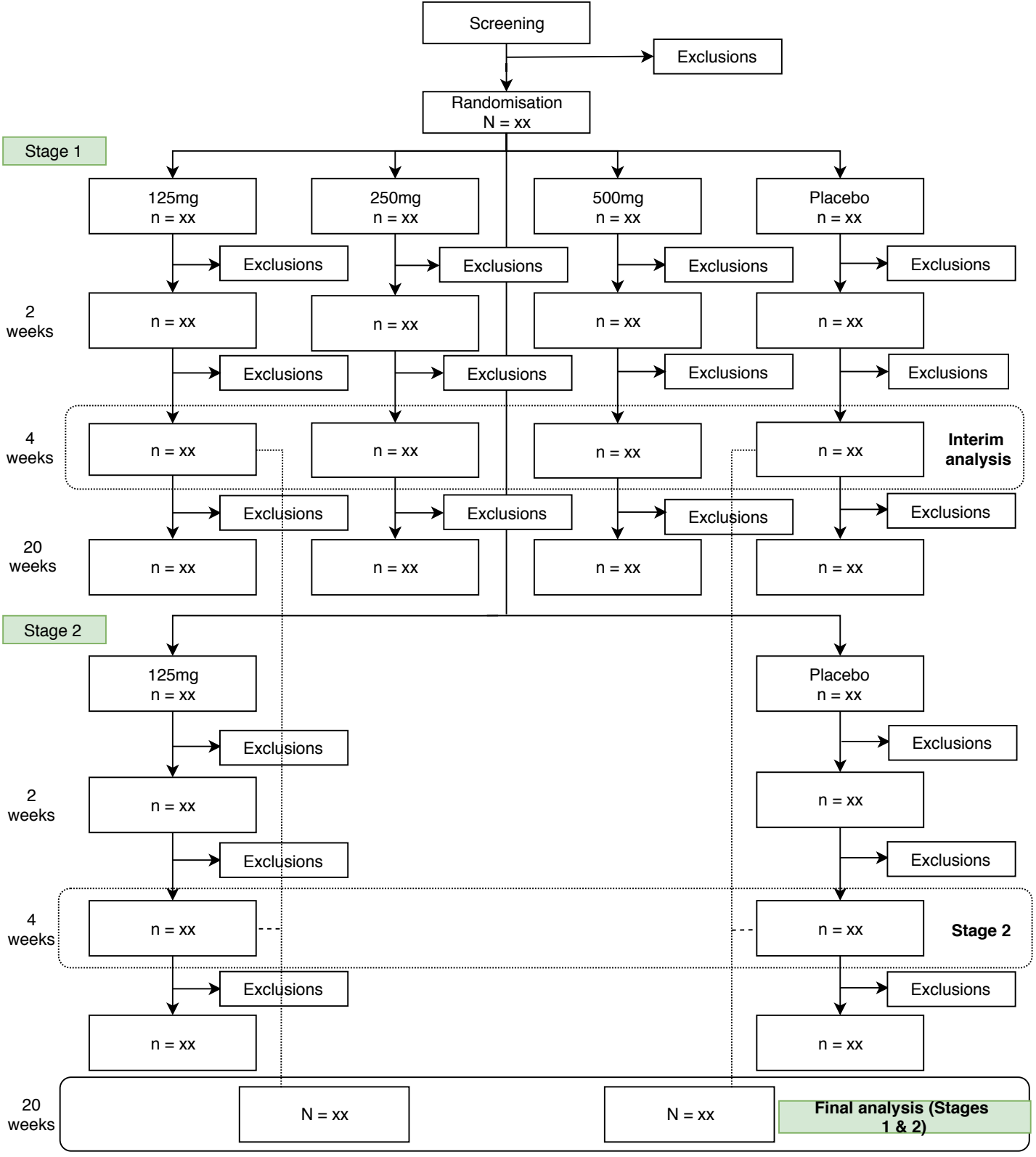
Screening
Exclusions
Randomisation
N = xx
Stage 1
125mg
n = xx
250mg
n = xx
500mg
n = xx
Placebo
n = xx
Exclusions
2 weeks
n = xx
4 weeks
Interim analysis
20 weeks
Stage 2
Stage 2
Final analysis (Stages 1 & 2)
N = xx