|  |  |  |
| --- | --- | --- |
| 1 | Doses under investigation? |  |
| 2 | Target toxicity level (TTL)? |  |
| 3 | Skeleton?  If no skeleton, which dose do you expect to be the MTD? You can use dfcrm::getprior to generate a prior. E.g.  getprior(halfwidth = 0.05, target = 0.2, nu = 4, nlevel = 5)  will generate prior that anticipates dose-level 4 of 5 is the sought dose with associated Prob(DLT) = 0.2. Tweak halfwidth to get a prior that you agree with. |  |
| 4 | Starting dose?  This might be lower than your guess at MTD.  Do you have doses to de-escalate to, if your assumptions are wrong? Painful to stop a trial due to poor planning. |  |
| 5 | Model type? |  |
| 6 | Model parameters, including prior hyperparameters? |  |
| 7 | How to select dose?  Describe constraints, like “no skipping in escalation” or “at least two complete negative DLT evaluations before escalation” |  |
| 8 | How to know when to stop?  Describe constraints like “use no more than 30 patients” or “stop early if lowest dose is too toxic” |  |
| 9 | Length of DLT assessment window |  |
|  |  |  |
|  | **If using non-time-to-event method:** |  |
| 10 | How to select cohort size? |  |
|  |  |  |
|  | **If time-to-event method:** |  |
| 11 | How to calculate weight of observation from length of follow-up? |  |
|  |  |  |
|  | **For simulation:** |  |
| 12 | What is assumed true Prob(Tox)? |  |
|  | **If time-to-event method:** |  |
| 13 | How to sample time between consecutive patients? |  |
| 14 | How to sample time of toxicity, given that toxicity happened? |  |