# Graphical user interface Description automatically generated with medium confidence

# Clinical Trials Advisory Board (CTAB) – Application Form

All applicants are expected to complete this if invited to full submission.

This form should be no more than 5 sides at size 11 font.

1. **SUMMARY**

|  |  |
| --- | --- |
| Full title |  |
| Short title/Acronym |  |
| Trial type  e.g. observational, intervention |  |
| Clinical phase |  |
| Sponsor |  |
| Principal investigator |  |
| Other team members |  |
| Please list any conflicts of interest for the Principal Investigator and any other team members. If none, please state this. |  |
| Lead Institution |  |
| Trial Population |  |
| Trial Interventions | |
| Experimental |  |
| Control (if applicable) |  |
| Sample size |  |
| Trial duration |  |
| Planned recruitment | Estimated date of first patient enrolled:  Anticipated recruitment period: |
| No of Participating sites |  |
| FUNDING |  |

1. **DETAILED INFORMATION**

|  |  |
| --- | --- |
| 2.1 | **What is the main objective of the trial?**  (What is the trial hypothesis and the question intended to be answered) |
| 2.2 | **What is the proposed trial design?**  e.g. randomised phase II |
| 2.3 | **What is the rationale for performing this trial?**  *Include a short summary of results/conclusions from prior studies or pilot data,*  *or from a systematic review, as appropriate* |
| 2.4 | **If the proposed trial is positive, what further studies would you plan to do?** |
| 2.5 | How does this proposal work within the current clinical trials strategy for this particular tumour type? |
| 2.6 | **What are the characteristics of the population under study?**  Principal eligibility criteria |
| 2.7 | **What are the planned trial interventions?**  Protocol treatments for each arm |
| 2.8 | **If this is a trial of an investigational medicinal product (IMP) is it available and could it be commercialized?** |
| 2.8.1 | **What is the pharmacology of the proposed IMP(s)?**  *Drug potency, selectivity, proof of concept, advantages over competitive approaches.*  *Pharmacokinetics (time course upon administration) and pharmacodynamics (intensity of effect).* |
| 2.8.2 | **What is the formulation and administration of the proposed IMP?**  *Especially the relationship between dosing in the non-clinical studies and subsequent clinical trials. Is there appropriate justification for the scaling up of dosing? Is the route of administration compatible with clinical trials?* |
| 2.8.3 | **Evidence of safety**  *Please provide a summary of safety evidence. Where the target population is paediatric, what previous paediatric regimes have been used? If there is a perspective for long term use, do previous studies reflect this or would further studies be needed to extrapolate to different populations or duration of dosage?* |
| 2.9 | **What investigations differ from the usual medical practice for this disease?** |
| 2.10 | **What are the endpoints (outcome measures) and statistical design?** |
| 2.11 | **Do you have any intention to undertake pharmacokinetic/pharmacodynamic studies?**  *Measurements and endpoints considered? Justify.* |
| 2.12 | **Do you have any intention to undertake translational, biomarker or biorepository studies?**  *Markers and endpoints considered? Justify.* |
| 2.13 | **Has PPI/Caregiver input been sought?**  If so, please detail |
| 3.1 | **Clinical Trials reference number (clinicaltrials.gov)** |
| 3.2 | **Planned IRB name** |
| 3.3 | **IND or an IND exemption**  *(their local* regulatory *authority equivalent in other countries where the trial will be conducted)* |
| 4.1 | **What specific areas would you like feedback on from the CTAB?** |