Template Application Price/Award IAG-KHT

Protocol synopsis (outline) form

# Study information

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| --- | --- |
| Title |  Recommended format: "ALIAS: Question, patient population: type of study. Example: Phase III study assessing the “best of” radiotherapy compared to the “best of” surgery (trans-oral surgery (TOS)) in patients with T1-T2, N0-N1 oropharyngeal carcinoma” |
| Short title(max 50 characters) |   |

|  |  |  |
| --- | --- | --- |
| Study Coordinators |  Name | Institution: |
| (further) Studyco-Coordinator |  Name | Institution: |
| Other centers involved | [ ]  Yes[x]  No[ ]  Not confirmed | Center(s) name:  |

|  |  |
| --- | --- |
| Sponsorship |  IIT, company, independendend grant |
| Names and contacts of 3 independent external reviewers |  The proposed reviewers should not be involved in development of the proposal |

# Concept

|  |  |
| --- | --- |
| Study background |  Please use Mendeley for references in the text and put the bibliography at the end of the document. |
| Rationale and relevance for patients and the scientific community |  |
| Current standard therapy |  |
| Patient population (disease characteristics, patient characteristics and prior or concurrent therapy)  |  |
| Main objective |  |
| Secondary objective(s) |  |
| Study design |  |
| Integrated biomarker assessment (if not std)  |  If applicable, you should describe here the screening phase /biomarker assessment.Description of the assay platform/ imaging technique to be used and data that support the use of the assay for the defined role or, if such data do not exist, explanation for why this assay/ technique was chosen.Biosample/ imaging data collection: specify specimen type and amountNote: if the material is kept for biobanking, please also complete the “Biobanking” section below.Name of central laboratory and responsible person for BM testing.If know, specify if the laboratory holds specific accreditation(s) or participates in external quality assurance (EQA) rounds for the BM testing. |
| Describe treatment group(s) |  Describe the dose and schedule of the treatments including treatment duration. |
| Study scheme |  If applicable please add at the end of the document |

# Statistics

|  |  |
| --- | --- |
| Primary endpoint(s) also specify the parameter used in the statistical design |  e.g. OS, we will use OS at 5 years or definition of DLT for Phase I |
| Secondary endpoint(s) |  |

# Stats for primary endpoint

\* delete rows for stats designs as applicable

|  |  |
| --- | --- |
| Type of study design | Choose one of the following and delete the rest: Feasibility, Phase I single agent, Phase I combination, Phase I/II, Early phase II, Late phase II, Phase II/III, Phase III superiority, Phase III non inferiority / equivalence, TR only, Biobank, Survey, registry or Other |
| Is the study randomised | If yes, specify the timing of randomisationGive stratification factors |
| Phase II\* | Design: A’Hern/ Simon/ Korn/ Bryan and Day/ Sargent and Goldberg/ other (if other, specify)null hypothesis:alternative hypothesis as used for the power calculation: total number patients (all steps)

|  |  |
| --- | --- |
| type I and type II errors  | Alpha……… Beta……….. |
| critical number of successes necessary to continue/reject null hypothesis  | stage1…..….successes# /……… patients$, # The minimum number of successes in order to proceed to Stage 2 of the trial$ Minimum number of patients required to be accrued to conduct Stage 1 of the trialtotal …..…. successes# / …..…. patients$ # The minimum number of successes to indicate that the treatment is effective$ Minimum number of patients required to be accrued to conduct the trial |

if not classical Simon, specify decision rule at each stage of the design |
| Phase III superiority\* | null hypothesis including estimate for control group: alternative hypothesis as used for the power calculation:

|  |  |
| --- | --- |
| type I and type II errors  | Alpha …… Beta …….sides 1/2 sided |
| number of events/ patients  | ………events ……… patients  |
| expected duration of recruitment  | ……… months/years |
| expected duration of follow-up after end of accrual  | ……… months/years |

 |
| Phase III non inferiority / equivalence\* | null hypothesis including estimate for control group and delta of inferiority or equivalence:alternative hypothesis as used for the power calculation:

|  |  |
| --- | --- |
| type I and type II errors  | Alpha …… Beta …….sides 1/2 sided |
| number of events/ patients  | ………events ……… patients  |
| expected duration of recruitment  | ……… months/years |
| expected duration of follow-up after end of accrual  | ……… months/years |

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| Statistical design other than those listed above including 2x2 factorial designs |  |
| Further details of statistical design | Parameters (i.e. null hypothesis, alternative hypothesis, significance level, power, number of interim analyses, early stopping rule, etc.) of the statistical design and required sample size. |
| Reference for reference value of design | Give the reference/paper on which you base the reference value for the control arm assumption |
| Planned early stopping rule or interim analysis | If yes give details |
| Will this trial be monitored by an IDMC |  |

# Correlative Translational Research (TR)\*

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| --- | --- |
| Purpose of correlative TR | Please choose one of the following:Biomarker discoveryBiomarker assay developmentBiomarker qualification (confirmation validation)Phamacokinetics / PharmacodynamicsOther |
| Background and rationale for the TR project (with appropriate literature review and references). |  |

# Reference

|  |  |
| --- | --- |
| References | Bibliography should be listed here, max 15 key references |

Guidelines are provided in red, all red text should be deleted before the outline is submitted.
Please provid a study scheme here if applicable

\* if applicable/ or delete