NCRI Proposal Guidance: Proforma.

Please kindly refrain from sending the entire proposal/protocol and keep to a page limit of 5 pages.

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| Lead Researcher details | | |
| Title |  | |
| First name |  | |
| Surname |  | |
| E-mail address |  | |
| Phone number |  | |
| Institute |  | |
| Research Areas | | |
|  | Please specify below: | |
| Study overview | | |
| Study name |  | |
| Researchers |  | |
| Background and hypothesis | * [Patient population – who affected, how many] * [Typical management] * [Current therapy options] * [Problems, uncertainties with current options – e.g. survival, toxicities, difficulty in predicting who will benefit] * [Prior pre-clinical work – please see Appendix] | |
| Aim of study | * [Main question this trial will address] * [How this builds on the existing evidence base] | |
| Proposed source(s) of funding | [Please specify funder and funding call:] | |
| Estimate of funding required |  | |
| Patient and public involvement | | |
| Lay summary up to 300 words (Required) | * [Define in lay terms why the trial is needed, the basic design of the trial, how the treatment differs from current clinical practice, and how the trial results will be used / of benefit to patients] * [Check out https://www.rds-london.nihr.ac.uk/resources/tips-for-writing-a-lay-summary/ for tips on “How to write a good lay summary”] | |
| Outline of patient and public involvement | * [Has patient input to the proposal/trial design been sought?] * [Is there a plan to get patient input for the patient information sheet etc if funded?] | |
| Patient representatives with specific skills or experiences | * [Please specify below and we will try to accommodate] | |
| Challenges/questions on which you would like feedback on | * [Please specify below] What questions and challenges do you want PPI input on * What do you hope a patient representative will contribute to your research? | |
| **Patients** | | |
| Estimated number of patients | * [please justify the sample size required] | |
| Main  inclusion criteria |  | |
| Main  exclusion criteria |  | |
| **Intervention** | | |
| Trial Phase | | Pre-clinical ☐  Phase I ☐  Phase II ☐  Phase III ☐  [If applicable] |
| Study Design | | * [Randomised/non-randomised; single centre/multicentre, Phase 1, 2, 3, feasibility, observational etc.] * [Include flow chart of study design where available - you can upload this at the end of the page] |
| Treatment or Intervention | |  |
| **Comparator** | | |
|  |  | |
| **Outcomes** | | |
| Outcome measures / endpoints | * Primary endpoint * Secondary endpoints | |
| Basic statistical concepts |  | |
| **Translational research** | | |
| Have you had translational / biomarker input? If so, from whom? |  | |
| Type of biomarkers | Predisposition ☐  Screening ☐  Diagnostic ☐  Prognostic ☐  Predictive ☐  Pharmacological ☐  surrogate response ☐  Other ☐  n/a ☐ | |
| Biomarker test | Provide detail of biomarker test:  DNA and RNA sequencing ☐  genomic microarrays ☐  DNA methylation ☐  PCR ☐  Proteomics ☐  Metabolomics ☐  circulating tumour cells and cell-free DNA ☐  Immunohistochemistry ☐  in situ hybridisation ☐  Other ☐  n/a ☐ | |
| Type of imaging | PET ☐  MRI ☐  CT ☐  Other ☐  n/a ☐ | |
| Sample collection? | Please specify: | |
| Future translational hypothesis to be tested? |  | |

|  |  |
| --- | --- |
| General information about your proposal status | |
| If the proposal has not been submitted for funding, would you say the proposal is almost ready for funding, can be submitted within 6 months, or at a very preliminary stage? | Almost ready for submission  Can be submitted within 6 months  At a very preliminary stage |
| Have you had statistical input? |  |
| Which CTUs or RDS are you working with? |  |
| Are there any specific areas you need help with?  Please indicate what specialism(s) you require? |  |

Appendix

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| Prior pre-clinical work | |
| Hypothesis to test |  |