Call for Radiotherapy proposal ideas - CTRad Proposal Guidance meeting

Please kindly refrain from sending the entire proposal / protocol and keep to a page limit of 7 pages. On the online submission page there is an option to upload a study flow chart.

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| Submission date: dd/mm/yyyy  |
| Researcher details |
| Lead Researcher’s name |  |
| Other researchers’ names |  |
| Study overview |
| Study name |  |
| Background and hypothesis | * [Patient population – who affected, how many]
* [Typical/standard 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 / scientific question | * [What is the scientific question?]
* [Please describe the primary aim(s) of the proposed study]
* [Main question this trial will address]
* [How this builds on the existing evidence base]
 |
| Proposed source(s) of funding | * Which funder(s) are you considering?
 |
| Estimate of funding required | * Have you performed cost estimates of your proposed study?
 |
| 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 the document ‘[How to write a good lay summary](https://www.ncri.org.uk/wp-content/uploads/CTRad-How-to-write-a-good-lay-summary-Jan-2021.pdf)’]
 |
| 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?]
 |
| Intervention & comparison |
| Trial phase |  |
| Study / Trial design | * [Randomised/non-randomised; single centre/multicentre etc.]
* [Include flow chart of study design where available and describe the treatment arm(s)]
 |
| Treatment or intervention |  |
| Comparator |  |
| Patients |
| Estimated number of patients |  |
| Maininclusion criteria |  |
| Mainexclusion criteria |  |
| Outcomes |
| Outcome measures / endpoints | * Primary endpoint
* Secondary endpoints
 |
| Basic statistical concepts |  |
| Translational research |
| Have you had translational / biomarker input? If so, from whom? |  |
| Outline of any translational/ biomarker/ imaging components |  |
| Sample collection? |  |
| Future translational hypothesis to be tested? |  |

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| General information about your proposal status |
| RT Quality Assurance - Have you discussed your proposed study with the RTTQA group? |  |
| Has the proposal already been submitted for funding? If so, where? |  |
| If the answer to the previous question is yes, please provide relevant dates and the outcome: |  |
| If the proposal has not been submitted for funding, would you say the proposal is almost ready for funding, can be submitted within 6-12 months, or at a very preliminary stage? | [ ]  Almost ready for submission[ ]  Can be submitted within 6 months[ ]  Can be submitted within 1 year[ ]  At a very preliminary stage |
| Have you had statistical input? | If yes, what statistical advice have you received? |
| Which CTUs or RDS are you working with? |  |
| Have you had input from CTRad members / CTRad Workstream(s) / relevant NCRI Group(s)? If so, please specify who/which group(s):  |  |
| Future leaders – Have you identified a trainee interested in clinical trials to be involved in your study? |  |

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| **Benefits from this Proposal Guidance meeting**  |
| How can we help? | [Please list up to three items] |
| What are the challenges? | [Please list up to three items] |

Appendix

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| Prior pre-clinical work |
| Hypothesis to test |  |
| Any data justifying hypothesis and study plan | * [For example: schedule (not just of IR but order in which drug is given – before or after IR and length of interval), dose]
* [a. Pre-clinical cell line data]
* [b. Preclinical animal models]
 |
| Does pre-clinical data suggest patients should be selected on basis of a biomarker? | * Please provide description (unless the purpose of the study is to find out)
 |
| Does the preclinical data suggest a different toxicity profile from conventional IR? |  |

**Please fill out these extra questions if you are submitting a Proton Beam Therapy proposal:**

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| **Study Overview** |
| Pilot data and planning studies | * What pilot data are available to support your proposal
* Have any planning studies been performed? If they are underway, please provide timelines
 |
| If study is Evaluative Commissioning, describe clearly why is a trial not possible? |  |
| **Development of Study or Trial Concept** |
| PBT Centre Involvement | * Have you discussed your proposal with a UK NHS PBT Centre?
* Have you involved a member of a UK NHS PBT Centre in its development?
 |
| Internationallandscape | * What trials are planned/running internationally in the disease area you plan to study? Is there scope for international collaboration?
 |
| **Commissioning Impact** |
| Likely NHS commissioning impact | * If the trial or study were to have a positive result, what would the likely impact be on patient numbers recommended for routine access to PBT?
* Give a rationale for these numbers
* Is the study within the scope of a current Clinical Policy? (link below)

<https://www.england.nhs.uk/commissioning/spec-services/highly-spec-services/pbt/> |