Study Concept Form

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| *(maximum of 10 pages in total, font size 10)* | |
| **Study Title:** *Please provide a title which encapsulates the objective(s) of the study proposal* | |
|  | |
| **Concept Version:** | No dd-mon-yyyy |
| **Chief Investigator:** | Name of Chief Investigator |
| **Are there other modalities needed (e.g. radiotherapy, surgery, medical oncology, transplantation)?** | |
| **No**  **Yes** | |
| **If Yes, please provide name(s) of potential co-Chief Investigator(s):** | |
| Name of Co- Investigator (if applicable) | |
| **How many sites are needed?** | |
| In Ireland: Number of Irish sites  Outside Ireland: Number of non-Irish sites | |
| **Background & Hypothesis:** | |
| * *patient population* * *typical management* * *current therapy options, problems, uncertainties with current options – e.g. survival, toxicities, difficulty in predicting who will benefit* * *prior pre-clinical work* | |
| **Aim of the study** | |
| * *Main question this trial will address* * *How this trial/study builds on the existing evidence base* | |
| **Lay Summary** | |
| * *Define in lay term 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* | |
| **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/approved* | |
| **Main inclusion criteria** | |
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| **Main exclusion criteria** | |
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| **Intervention: Trial Phase** | |
| not applicable Pre-clinical  Phase I  Phase II  Phase III | |
| **Study Design:** | |
| **Randomised**  **Non-randomised**  *Include flow chart of study design where available (can be attached to the form)* | |
| **Estimated length of:** | |
| Recruitment Phase: Number of months Treatment Phase: Number of months  Follow up Phase: Number of years | |
| **Treatment or Intervention and Comparator (if applicable)** | |
| *Name of the drug (s) and Comparator (s)*  Who supplies the drug? Name of the company(ies)  Are / is the drug(s) available in Ireland? Yes  No  Are there any other non-Standard of Care (SOC) tests needed? Yes  No  If Yes, name all of them: Name all non-SOC tests  If Yes, name the labs / hospitals who will do them: Name the labs / hospitals | |
| **Primary Endpoint(s):** | |
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| **Secondary Endpoint(s):** | |
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| **Is an Interim Analysis or early analysis (e.g.: futility analysis) planned?** | |
| Yes  No  **If Yes what triggers the analysis:** | |
| **Estimated number of patients** | |
| *Please justify the sample size required* | |
| **Basic statistical concepts** | |
| **Have you received statistical input YES  NO If YES from whom:**  *Please describe the basic statistical concept* | |
| **Is funding available for GCO YES**  **NO** **If YES please provide details** | |
| *Name of funding source, amount, etc.* | |
| **Is funding available for sites YES  NO If YES please provide details** | |
| *Name of funding source, amount, etc.* | |
| **Translational Aspect/ Analysis: Not applicable** | |
| *Describe the translational research:*   * *E.g., translational/biomarker/imaging components* * *Translational hypothesis to be tested* | |
| **Biological Sample Type/ Number:** *e.g. blood samples (what type), tissue, etc.; once off or longitudinal samples* | |
| **Biological Samples:** Name the biological samples to be collected/ analysed (*e.g., blood samples (what type), tissue, etc.)*  Is the collection of samples an once-off collection  or a longitudinal collection  If longitudinal how many collection time points are needed: | |
| **Is funding available for the Translational Aspect** | |
| **YES  If YES please provide details**  **NO  If NO what is the plan for funding the study** | |
| **Peer Review:**  *I agree that this Study Concept will undergo the peer review process as outlined in SOP 25.* | |

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| Name (please print) |  | Signature |  | Date |
| **General Data Projection Regulation (GDPR):**  *I consent to a) sharing of my data outside of the EU for the purpose of international peer review and b) the use of my data for assessment of the concept.* | | | | |
|  |  |  |  |  |
| Name (please print) |  | Signature |  | Date |