Advice to Applicants

Before submitting this Expression of Interest (EOI) to access the services provided by the Clinical Trialist Development Hub, please read the Guidelines to ensure the application meets the project requirements and addresses the assessment criteria.

All applications must be made using this EOI template, and submitted as a PDF to Duncan Colyer: Senior Manager, Clinical Research via email (duncan.colyer@unimelb.edu.au) by midnight Sunday 31 December 2023, with the subject line: CTDH EOI-SURNAME. Please attach as appendices any additional supporting documents that may be appropriate for your submission.

References can be included on the final page of this form.

No late applications will be considered.

Applicants contact details

Name of lead applicant

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Contact email address

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Contact mobile number (optional)

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Position (*Please list if multiple positions held*)

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VCCC Alliance institution (*Please list if holding multiple appointments*)

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Academic and clinical area of interest

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Project Details

Title of the clinical trial

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Does your clinical trial directly relate to a specific tumour type? If so, which?

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| (*eg. Tumour type: Breast Cancer; sub-type if applicable: HER2+ breast cancer)* |

Key Selection Criteria

Applications will be reviewed by a panel of experts and scored against the Key Selection Criteria described below. Responses will be scored against the weighting assigned for each criterion.

Study Design and Feasibility – 15%

Please provide an outline of the feasibility of the study including anticipated duration of recruitment and expected recruitment size.

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| *Max 100 words.* |

Please briefly outline the design and methodology for the proposed clinical trial

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| *Max 200 words.* |

Patient cohort – 15%

Please describe the patient cohort required to address the proposed study and how you will identify them.

If known, describe anticipated inclusion and exclusions.

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| *Max 100 words.* |

Clinical Significance and Benefit to Patient– 30%

Please provide a brief outline of the proposed trial Including rationale, identified novel therapy and potential benefits for the cancer community.

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| *Max 400 words.* |

 Clearly describe in lay terms how the proposed trial will benefit cancer patients.

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| *Max 200 words.* |

Innovation and Translation - 40%

Please provide details of how the proposed clinical trial provides patients with access to novel therapies that have not been offered previously. Explain how the proposed trial is innovative.

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| *Max 200 words.* |

Does the proposed trial have a translational research component?

☐ Yes ☐ No

If so, please provide details of the translational research component associated with this trial

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| *Include lab or organisation involved, cross VCCC Alliance collaborations, developing expertise in new areas, etc.* *Max 100 words.* |

Non-assessed Criteria

Responses to the following questions will not be scored. The information provided will assist with identifying the level of support the project requires and assembly of the appropriate expert panel to assist with trialist development.

Clinical Trial Team Experience

Provide a list of all investigators associated with this proposal and outline their experience in developing and establishing clinical trials.

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| *Max 100 words* |

Funding

If provided support from the Clinical Trialist Development Hub for protocol writing and biostatistical support, how do you plan to fund this trial?

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| *Max 100 words* |

Industry engagement / partnerships

Do you see an opportunity to collaborate with an Industry partner for this project?

☐ Yes ☐ No

If so, please provide details

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| *Max 100 words* |

If not, do you see potential for the outcomes of this clinical trial to attract industry partnership?

Please provide details.

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| *Max 100 words* |

Regional involvement

Will this trial be conducted either partially or entirely at a regional site?

☐ Yes ☐ No

If so, please provide details of the regional site/s and how they are involved in the proposed trial.

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 Additional comments

Please include any additional supporting information in the following section.

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References

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