Expression of Interest Guidelines Early Phase Clinical Trial Protocol Development Support

VCCC Alliance
Overcoming cancer together

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1.0 The Opportunity

The VCCC Alliance is committed to accelerating the translation of novel therapies into the clinic through early phase clinical trial activity to benefit patients with the greatest need.

Aspiring investigators from member organisations and regional partners have the opportunity apply for support to develop concepts that will assess novel therapies through early phase investigator-initiated trials (IITs) into protocols.

2.0 Background

2.1 The VCCC Alliance is investing in Early Phase Clinical Trials

The strategic goals of the Accelerating Novel Therapies Program is to drive the next generation of discoveries that address critical cancer challenges through collaboration. The benefit of this program is that more patients can access the right therapies in the right place at the right time.

2.2 The VCCC Alliance Clincial Concept Development Hub

The VCCC Alliance Clinical Trialist Development Hub will be delivered as part of the 2021-2024 SRP Accelerating Novel Therapies Program. The project intersects with several initiatives established through both the Personalised Cancer Care and Accelerating Novel Therapies programs by creating a framework that supports early/mid-career clinicians and researchers to set up multi-site research studies and trials across the Alliance. The outcome for patients will be increased access to novel therapies through more clinical trials.

The project leverages the lessons learnt through the SRP 2017-2020 Investigator Initiated Clinical Trials programs, which is that emerging Concepts require access to specialist support and mentoring to chaperone them through the process of trail design through to applying for ethics and funding.

By supporting the development of novel trial designs and upskilling the new generation of clinical trial investigators, the VCCC Clinical Trialist Development Hub will support the acceleration of the development of novel therapies.

2.3 What the VCCC Alliance Clinical Trialist Development Hub Offers.

The Clinical Trialist Development Hub will address the needs of emerging Concepts by providing a mechanism for to pitch early ideas and refine through peer-support workshops, access to biostatistics, and protocol writing. The Hub will also create and/or facilitate access educational material created by the VCCC Alliance education team.

The Clinical Trialist Development Hub will provide the following to applicants:

- Access to specialist services to support trial design including biostatistics and protocol writing
- Access to mentors and peer support for clinical trial establishment

If the support of the Clinical Trialist Development Hub is approved after submission of the proposal during the Expression of Interest process, applicants will be supported to prepare a 1-to-2-page summary that will be provided to the Clinical Trialist Development Hub team.

Applicants will then be invited to speak with an expert panel including but not limited to an experienced Concept, translational researcher, biostatistician, and a consumer. The objective is to develop the concept by looking for opportunities for translational research and commercialisation or industry engagement. Applicants will be supported to prepare a brief concept pitch to the panel. The panel will provide a report including constructive feedback and will determine a recommendation on whether the applicant will move through to the next stage of the Clinical Trialist Development Hub's supports.

The successful applicant will be provided with the support of a biostatistician and protocol writer to assist with the development of a completed study protocol.

3.0 Eligibility

For potential projects to be considered for the support of the Clinical Trialist Development Hub, concepts must:

- address an area of significant clinical need in cancer treatment
- be innovative with the potential for research translation
- provide patients access to novel therapies that have not been offered previously
- be in the early stage of development
- be feasible within the available support provided
- be led by an individual affiliated with one or more VCCC Alliance member site

4.0 Schedule for Submission

Expression of Interest process commences:	14 November 2022
Expression of Interest applications close:	31 December 2023

5.0 Application submission

The Clinical Trialist Development Hub Expression of Interest is available to download and submit via the VCCC Alliance website.

Completed applications must adhere to the following:

- Be completed using the Expression of Interest template, adhering to all word limits
- Applications should use plain-language and in 11-point Calibri font
- Approval from all listed co-investigators and/or mentors must be sought prior to submission
- References are to be included in the submission.
- Applications to be submitted electronically in PDF format to Duncan Colyer: Senior Manager, Clinical Research via email (duncan.colyer@unimelb.edu.au) by midnight Sunday 15 January 2023, with the subject line: CTDH EOI-SURNAME.
- Any supporting documents can be included as an appendix to the application if appropriate. Please keep the length of these to a minimum.

Questions regarding the opportunity may be submitted any time before the due date.

No late applications will be considered.

6.0 Review Process

Expressions of Interests will be reviewed by a working group comprised of academic, medical, and translational research experts across the VCCC Alliance. Expression of Interests will be reviewed against the criteria and weighting outlined in Appendix 1.

The top ranked project(s) will be invited to meet with the Clinical Trialist Development Hub project team for further discussion and involvement in the hub including progression into the Stage 1: Concept Development process.

If unsuccessful, applicants will be provided with written feedback to support any future applications.

Unsuccessful applicants are welcome to apply again for support in any future rounds.

7.0 Success Applicants

Successful applicants will be notified in the first quarter of 2023.

Successful proposals will be required to submit progress reports to the VCCC Alliance Accelerate Novel Therapies Steering Group at 6 months and 12 months and/or at the completion of the project.

Appendix 1: Expression of Interest Criteria

The Expression of Interest criteria that will be used by the expert panel and weighting is outlined below.

Innovation and Translation – 40 %

Applicants must demonstrate how a collaboration with the Clinical Trialist Development Hub will assist in answering an outstanding question in the field of human cancer and provide patients access to novel therapies that have not been tested before. Applicants should also indicate whether the proposed trial is associated with a translational research project and if any link to specific expertise or facility is required.

While there are no restrictions on area of interest, tumour stream or drug target, it is important that the Expression of Interest outlines how the proposed clinical trial provides access to novel therapy for patients with cancer.

The VCCC Alliance seeks to accelerate the implementation of evidence into routine practice and ensure new discoveries are translated from benchtop to bedside. Outline if the proposed trial has a translational research arm and include details on whether there is an existing collaboration is currently in place.

Clinical Significance and Benefit to Patient– 30 %

Applicants must outline how proposed trials will be innovating and address an area of significant clinical need. The rationale for the trial is to be detailed.

It is expected that the proposed trial will benefit cancer patients. Applicants are to outline benefits for patients and any consumer engagement that could be considered.

During the Expression of Interest application, please refer to the novelty of the proposed trial and how the proposal can address an area of significant clinical need, particularly in areas or with therapies that are understudied.

The VCCC Alliance strives to amplify the consumer voice in everything we do, because no one knows cancer like someone who's lived it (**link**). Please ensure care is taken in describing the benefit to patient and that language used is non-technical and can be easily understood by a lay audience. The VCCC Alliance Consumer Engagement Toolkit (**link**) can be helpful. It is recommended that consumers are involved in the early development of your concept and Expression of Interest submission including through the review of your lay summary.

Study design and Feasibility– 15 %

Applicants are to have a detailed study design and clear methodology planned for the proposed clinical trial. Project plans are expected to include details of:

- Samples to be used for research purposes including any requirements for collection
- Expected outcomes
- Proposed timelines
- HREC and governance approvals

Ensure the study design is clear, concise, and adheres to the page limit. If the Expression of Interest is successful, further support will be provided to develop the study design and study methodology.

The Hub does not provide funding for clinical trials or research projects after the protocol has been developed, but resources including educational materials are available for further support.

It is important that the proposed study is feasible in its patient recruitment. Please outline how you intend to access a patient population if targeting a rare cancer or mutation, for example.

Patient cohort – 15%

Applications are to describe the patient cohort required to address the proposed study and how the patient population will be accessed. It is expected that the following details are included:

- Inclusion and exclusion criteria

- Sample size
- If rare diseases are clinically indicated, how will patients be recruited?

Non-Assessed Criteria

Patients with cancer living in regional and rural Victoria experience several disadvantages including lower survival rates and barriers to clinical trial access (time, cost and social disruption) compared to patients living in Melbourne. If possible, outline in the Expression of Interest whether the trial will be conducted either partially or entirely at a regional site.

Developed in partnership with the Melbourne Academic Centre for Health (MACH), resources on investigated-initiated trials are available through the VCCC Alliance including support on:

- Roles and Responsibilities
- Clinical Trial Life Cycle
- Clinical Trials Budget
- Risk Management
- Data Management
- Monitoring
- Resources
- Glossary