

## Call For New Trial Concepts

You are invited to submit a New Trial Concept for presentation at the **ANZGOG ASM 2022**, to be held in Melbourne, 23 - 26 March 2022.

Proposals may be for any type of clinical research in gynaecological cancer e.g. clinical trials, epidemiological studies, translational studies, psycho-social research etc.

Concepts that are submitted for review for the ASM 2022, can either be presented:

1. To the relevant Tumour Working Group for input into further development; OR
2. At the New Concepts session at the ASM on Friday 25 March 2022 and then for RAC review during the ASM as a potential future ANZGOG study. This path is for study proposals that are already well developed and ready for RAC scientific review.

You will receive feedback on the best pathway option for your concept after our initial Concepts Review prior to the ASM.

Selection for the New Concept session at the ASM will focus on new clinical trials or sub studies of current ANZGOG clinical trials. Concepts meeting the OASIS Initiative criteria will also be considered.

Criteria for **OASIS Initiative** research:

- Investigating new drug therapies that target individual molecular subtypes of ovarian cancer.
- Phase Ib/II signal seeking clinical trials.
- "Home grown" studies developed by Investigators from Australia and New Zealand.
- Strong scientific rationale, with preclinical or pilot study data.
- Studies with a translational backbone, within a clinical trial.
- Studies with potential to be expanded to a Phase III study (if primary endpoint met).
- Completion of recruitment within reasonable timeframe ie 2 years or less. (Exceptions permitted for rare tumours.)
- **Applicants must be ANZGOG members.**

## Examples Of Successful Concepts

Concepts from previous years that have resulted in clinical trials:

- The Phaedra Clinical Trial – A Phase II trial of durvalumab in advanced endometrial cancer conducted with support from AstraZeneca Pty Ltd. PI Yoland Antill. This study investigated an immunotherapy drug, Durvalumab, in endometrial cancer. Initially presented as a concept at the ASM in 2016, subsequently the study was completed and presented at ASCO as an oral abstract 2019, showing promising activity and safety in a subgroup of women with endometrial cancer.
- The ECHO Trial – A Phase III trial evaluating the effect of an exercise intervention among women undergoing chemotherapy for ovarian cancer. PI Sandi Hayes. Funding from Cancer Australia (\$1.2M) and Cancer Council Queensland (\$2M). This trial will identify whether incorporation of an exercise program

into the current standard of care for women undergoing chemotherapy for primary ovarian cancer is an effective and cost-effective way to improve health outcomes in this patient group. Presented to the ANZGOG RAC in November 2012 and has now opened at 8 ANZGOG sites (with 1 more currently pending) and still accruing.

## Assistance With Concept Development

### 1. Statistics

ANZGOG group statistician Professor Val Gebski ([val@ctc.usyd.edu.au](mailto:val@ctc.usyd.edu.au)) and his team can assist:

- Endometrial/Uterine studies – Liz Barnes ([Liz.Barnes@ctc.usyd.edu.au](mailto:Liz.Barnes@ctc.usyd.edu.au))
- Ovarian studies – Rachel O'Connell ([rachel@ctc.usyd.edu.au](mailto:rachel@ctc.usyd.edu.au))
- Cervical studies - Kristy Robledo ([Kristy.robledo@ctc.usyd.edu.au](mailto:Kristy.robledo@ctc.usyd.edu.au))

### 2. Health Economics

The team at [CREST](#) can also provide advice from a health economics standpoint (looking at resource utilisation, quality of life, patient preferences or research questions focusing on practice change).

Contact Richard de Abreu Lourenco at +61 2 9514 4729, [Richard.deabreulourenco@chere.uts.edu.au](mailto:Richard.deabreulourenco@chere.uts.edu.au)

### 3. Quality of Life

The CQUEST team is available to assist with your concept as well. Contact Brendan Mulhern on [brendan.mulhern@uts.edu.au](mailto:brendan.mulhern@uts.edu.au) or phone +61 2 9514 4725.

## Guidelines for completing your concept

Please refer to the following guidelines for further information.

### CONCEPT TITLE

- Should be in the PICO format (ie the title should hold information on the participants, Intervention and Comparison groups, and the Outcomes of the trial).

### BACKGROUND AND SIGNIFICANCE

- Have you addressed the scientific validity?
- Is it an important question?
- Size of population defined?
- Sufficient rationale to proceed?
- Is it clinically relevant?
- Have you searched ANZCTR and other registries? [www.anzctr.org.au](http://www.anzctr.org.au)

### STUDY SUMMARY

- Aims:
  - i. Are they clearly stated?
- Trial objectives:
  - ii. Do they match aims?
- Hypotheses:
  - iii. Are they clearly stated?

- iv. Do they match aims and objectives?
- Endpoints:
  - v. Are they measurable?
  - vi. Are they suitable to answer trial questions?

## **STUDY DESIGN AND STATISTICS**

- Phase of study?
- Is design appropriate to address the question?
- Are treatment arms clearly described?
- What is the sample size estimate?
- Is the sample size justified in terms of primary endpoint?
- Is the study likely to detect a clinically significant difference?
- Has a statistician reviewed the study design?
- Is the study feasible? Outline the proposed sources of subjects and estimated recruitment rates.

## **SUBJECT POPULATION**

- Target population and setting should be described briefly. Main inclusion criteria – are they clearly stated and clinically relevant?

## **STUDY INTERVENTION**

- Briefly describe actions to be taken

## **FUNDING**

- Is there any financial support for the study?

## **TRANSLATIONAL RESEARCH**

- Is there a translational research component? Briefly describe any rationale, pilot data and methods, including anticipated biospecimen collection, if known.
- TR-ANZGOG Network Laboratory support is available to assist with collection, processing and storing biospecimens for ANZGOG trials, and provision of specialised media as required.
- The TR-ANZGOG Biospecimen Processing Manual (available upon request to the Project Manager, TR-ANZGOG), outlines flexible, standard processing recommendations for a variety of biospecimen types. Please liaise with the Project Manager, TR-ANZGOG [Claire.Davies@anzgog.org.au](mailto:Claire.Davies@anzgog.org.au) regarding trial requirements, if applicable.

## **OTHER**

- Have QOL and Health Economics assessments been included?
- Is there collaborative support from other trials groups

## **DEADLINE FOR SUBMISSION: Monday, 31 January 2022**

All presenters must register to attend the conference. Acceptance of papers into the program is contingent upon receipt of the registration fee in full.

### **Important Dates**

Concept Submissions Open – October 2021	October 2021
Early Bird Registration Deadline EXTENDED – 31 January 2022	31 January 2022
Concept Submission Deadline - Monday, 31 January 2022	Monday, 31 January 2022
Concept Acceptance Emailed – 18 February 2022	18 February 2022
Deadline for Speaker Registration – 28 February 2022	28 February 2022
Presentation of Concept at the ASM - Friday, 25 March 2022	Friday, 25 March 2022