CALL FOR NEW TRIAL CONCEPTS

You are invited to submit a New Trial Concept for presentation at the *ANZGOG Annual Scientific Meeting 2019*, to be held at the Sofitel Wentworth, Sydney, 20th – 23rd March 2019.

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

Concepts that are submitted for review for the ASM 2019, can either be presented:

1. To the relevant Tumour Working Group for input into further development on Wednesday, 20th March 2019; OR
2. At the New Concepts session at the ASM on Friday 22nd March 2019 and then for RAC review as an ANZGOG future study.

Your preferred submission option should be indicated on the Concept Submission Form. You will receive feedback on the best pathway for your concept as an ANZGOG study after our initial Concepts Review prior to the ASM.

Selection will focus on concepts for 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 EXCISE Study – Excisional treatment Comparison for In Situ Endocervical adenocarcinoma. PI Paul Cohen. This pilot study may lead to the first prospective randomised trial to compare LEEP (loop electrosurgical excision procedure) to CKC (cold knife cone biopsy) in conservatively treated AIS (adenocarcinoma in situ), and therefore enhance prevention of cervical adenocarcinoma whilst reducing morbidity and cost, and improving quality of life. Presented at the ASM in 2016 and received funding for a pilot study from the ANZGOG Fund for New Research in 2016.

- The Phaedra Clinical Trial – A Phase II trial of durvalumab in advanced endometrial cancer is conducted with support from AstraZeneca Pty Ltd. PI Yoland Antill. This study will be examining whether the drug Durvalumab can be used to treat endometrial cancer. It is a drug that potentially can stimulate the body's own immune system to fight the cancer. Presented at the ASM in 2016.

- The ECHO Trial – A Phase III randomised, controlled trial evaluating the effect of an exercise intervention among women undergoing chemotherapy for ovarian cancer. PI Sandi Hayes. Funding Cancer Australia and Cancer Council Australia $600,000. 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 Research Advisory Committee in November 2012.

DEADLINE FOR SUBMISSION: Thursday 20 December 2018

Concepts received by the deadline will be assessed for their pathway through ANZGOG for adoption as an ANZGOG research project. Investigators will be advised of the status of their concept prior to the publication of the Annual Scientific Meeting Program and Heshani Nesfield will continue to liaise with Investigators up to the ASM and with advice following the meeting. If you have any queries, please contact hnesfield@anzgog.org.au

Please refer to guidelines on next page for further information.

All presenters must register to attend the conference. Acceptance of papers into the program is contingent upon receipt of the registration fee in full. Preference is for all concepts to be submitted online.

IMPORTANT DATES

Concept Submission Deadline	Thursday, 20 December 2018
Presentation to the relevant Tumour Type Working Group	Wednesday, 20th March 2019
Presentation of Concept at ASM	Friday, 22nd March 2019

ASSISTANCE WITH CONCEPT DEVELOPMENT

1. STATISTICS

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

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

2. HEALTH ECONOMICS

The team at CREST can also a 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

3. QUALITY OF LIFE

The Quality of Life Office is available to assist with your concept as well. Contact Rebecca Mercieca-Bebber on rebecca.mercieca@sydney.edu.au or phone +61 2 8627 1558.

Guidelines for completing your concept

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

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:
  i. Are they measurable?
  ii. 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?

OTHER

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