



CALL FOR NEW TRIAL CONCEPTS

You are invited to submit a New Trial Concept for presentation at the *ANZGOG Annual Scientific Meeting 2017*, to be held at the Grand Hyatt, Melbourne from 29 March – 1 April 2017.

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

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.

The **OASIS Initiative** criteria includes 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 from previous years that have resulted in clinical trials:

- Can the addition of a lifestyle intervention improve the efficacy of a Levonorgestrel Intrauterine Device to treat complex atypical hyperplasia or grade 1 endometrioid endometrial cancer? - first presented as a new concept by Dr Andreas Obermair in 2011 and now the ANZGOG feMME trial.
- The effect of a nursing and peer support program to reduce anxiety in women with gynaecologic cancers being treated with radiotherapy - first presented as a new concept in 2008 by Dr Penny Schofield and now the ANZGOG PENTAGON trial.
- Adjuvant chemotherapy for high risk cervical cancer - Presented as a concept in 2008 by Dr Linda Mileskin and has become the Phase III OUTBACK GCIG trial, led by ANZGOG. If positive, it is likely to lead to a major change in cervical cancer practice internationally, and mark the first major advance in this malignancy for over a decade.

Usually, new proposals to ANZGOG are submitted to the Research Advisory Committee (RAC) for review of scientific merit and feasibility, prior to full protocol development. However, the New Trial Concept session at the ASM is designed to encourage open discussion of concepts that have the potential for further development, and to provide investigators with relevant feedback. The discussion will take place in an informal and unthreatening environment.

DEADLINE FOR SUBMISSION: ~~27th February 2017~~ now extended to the 6th March 2017



ASSISTANCE WITH CONCEPT DEVELOPMENT

1. STATISTICS

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

- Endometrial 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 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.

Where possible submitted concepts should address the following headings:

- (i) aims
- (ii) background and significance
- (iii) study summary including hypothesis, objectives, endpoints
- (iv) key eligibility criteria
- (v) statistical considerations.

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	6 th March 2017
Presentation of Concept at ASM	Friday, 31 March

Any Questions?

Any issues in submitting your concept online please contact the ANZGOG Conference Secretariat 07 3368 2433 or email anzgog@yrd.com.au

SUBMIT CONCEPT



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