**OASIS 2019 CONCEPT SUBMISSIONS**

Submissions to OASIS are keenly encouraged from ALL members.

The OASIS initiative

* provides operational support and funding for *innovative signal-seeking Phase II* trials in well-defined subsets of patients with recurrent ovarian cancer.
* enables the talent and ideas of Australian and New Zealand ovarian cancer researchers to be fostered by ANZGOG

Trials submitted may be well developed and ready for review and funding *or* a basic idea seeking the experience of the OASIS initiative group for further development.

In the 2019 funding round a maximum of $500 000 will be allocated to any single successful trial. Trials submitted may require full or partial funding from OASIS.

OASIS funding is not for basic research.

|  |  |
| --- | --- |
| **8 July 2019** | **Applications close** |
| **4 October 2019** | **Final notifications to all applicants** |

**OASIS CRITERIA FOR RESEARCH PROJECTS**

All submitted concepts must meet **all** criteria listed below to be considered:

|  |
| --- |
| * Phase Ib/II signal-seeking clinical trial in ovarian cancer. |
| * Study developed by ANZGOG member located in Australia or New Zealand – “home grown” |
| * Collaboratively developed international study, with a meaningful contribution by an ANZGOG member in developing the study idea and protocol. |
| * Strong scientific rationale, with preclinical or pilot study data. |
| * Includes a translational backbone. |
| * Has potential to be expanded to / lead onto a Phase III study (if primary endpoint met). |
| * Recruitment will be completed in a reasonable timeframe (2 years or less). |
| * Requires full or partial funding support. |

Please direct any questions about OASIS, concepts, or the submission and review process to

Tracey Meares

ANZGOG Project Manager – Research Pipeline

email: [research@anzgog.org.au](mailto:research@anzgog.org.au),

Phone: 0466 714 329

**REVIEW PROCESS**

Begins Tuesday 9 July 2019

|  |  |
| --- | --- |
| 1. | ANZGOG administrative review including OASIS Initiative group if required |
| 2. | RAC Scientific review & recommendations of submissions for funding review |
| 3. | ANZGOG Funding Review of RAC supported applications |
| 4. | Board meet for ratification of proposed recipients |
| 5. | Final notifications to all applicants – **by Fri 4 October 2019** |

**GUIDELINES FOR COMPLETING THE OASIS APPLICATION**

**CONCEPT/PROTOCOL TITLE**

* Should be in the PICO format (i.e. 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) or www.clinicaltrials.gov

**STUDY SUMMARY**

* Aims:

1. Are they clearly stated?

* Trial objectives

1. Do they match aims?

* Hypotheses:

1. Are they clearly stated?
2. Do they match aims and objectives?

* Endpoints:

1. Are they measurable?
2. Are they suitable to answer trial questions?

* Provide supporting data as part of study summary.

**STUDY DESIGN AND STATISTICS**

* Phase of study? NB. All studies in the OASIS Initiative must be Phase Ib or Phase II studies.
* 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? This is mandatory for OASIS concept submissions.
* Is the study feasible?
  + Is it feasible to recruit the number of subjects required for the sample size in Australia and New Zealand, during a 1-2 year period? Would other countries need to be considered?
  + Outline the proposed sources of subjects and estimated recruitment rates. Provide details about how many sites would be engaged in Australia and New Zealand, how many patients are expected to be recruited at each centre.

**SUBJECT POPULATION**

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

**STUDY DRUG(S)**

* Have you contacted the pharma/biotech company or manufacturer about access and/or provision of study drug?
* If access to study drug will not be granted now, what are the timelines?

**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

**INSTRUCTIONS**

Please ensure that all fields are completed within the form, including a lay summary. If any information is missing, the form will be returned to the applicant for completion.

# 1. PRINCIPAL INVESTIGATOR

**Name of Principal Investigator**

|  |  |
| --- | --- |
| Name: | Organisation: |
| Speciality: | Email: |
| Phone: | Mobile: |

**Investigator/s**

Names of ALL Investigators should be supplied in the surname-last format with the initial in capital. Institutional affiliations should be indicated with superscript numbers following the author name.

All affiliations should contain institution, city and country.

Example:

J Smith1, S Doe1

1 Department of Oncology, XYZ Hospital, Sydney, Australia

Application must include a 1-page track record summary for each Investigator.

|  |
| --- |
| **Investigator/s (list all)** |
| **Affiliations (list all the institutions)** |

# 2. CONCEPT OVERVIEW

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| --- | --- |
| **Concept/Protocol Title** |  |
| **Study Phase** | Phase Ib  Phase II  Other |
| **Ovarian Cancer subset** | None  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Is this submission:**  For RAC review and OASIS grant funding?  A new idea requiring ANZGOG support for development into a concept for later funding? | |
| **MANDATORY: Lay summary for consumer review** (250 words) | |

# 3. CONCEPT DETAILS

*(5 page limit for this section)*

|  |
| --- |
| **Background and Significance** (including preliminary data)  **Study Summary**  Aims:  Hypothesis:  Objectives:  Endpoints: |
| **Subject Population** |
| **Study Procedures** |
| **Statistical Considerations** (including sample size estimate and justification): Have you received statistical input for your study design, sample size etc.? Yes  No   NB. Statistical review/input must be sought prior to concept submission. |

|  |  |
| --- | --- |
| **Feasibility** (Please consider access to study drug, recruitment timelines, competing studies, funding. When considering recruitment, please take into account incidence rate and size of population in Australia and New Zealand.) | |
| **Biospecimen Collection/Translational Research Considerations** | |
| **Quality of Life Assessment** (if applicable) | |
| **Health Economics** (if applicable) | |
| **Draft Protocol** (if available) | Attached:  Yes  No  In development:  Yes  No |

# 4. FINANCIAL SUPPORT

|  |
| --- |
| **FUNDING** |
| Draft budget must be attached (mandatory).  Will the OASIS grant being sought fully or partially fund your concept?  Fully  Partially  No funding sought  If the OASIS funding does not cover all costs:   * Do you have any other confirmed sources of funding?   E.g.: Local Institution, PI Trust Fund, International Collaborative Trial Group, Other  No  Yes  Provide details of confirmed or pending funding:   |  |  | | --- | --- | | **Funder** | **Amount** | |  |  | |  |  |  * Is ANZGOG support to secure additional funding for your concept of interest to you?   E.g.: pharma/industry funding, MRFF, philanthropic funds, government grants.  No  Yes |
| **PHARMA SUPPORT Study Drug(s) & Pharma Company(ies) Details** |
| Does this concept include the use of prescription medicines?  No  Yes  If yes, Drug(s): Company(ies):  Have you had discussions with the manufacturer about:   |  |  |  |  | | --- | --- | --- | --- | |  | No | Yes | Planned for a date in the future | | Supply of drug |  |  |  | | Additional funds for drug handling costs? |  |  |  | | Any other funding for the study? |  |  |  |   Pharma contact:   |  |  | | --- | --- | | Name |  | | Position / Title |  | | email |  | | Phone |  | |
| **List of other significant collaborators, including CRGs** |
| **Any other comments** |

Checklist for submission:

* Completed OASIS Concept Form
* Trial budget (draft or final)
* Principal Investigator’s CV
* 1-page track record summary for each Investigator