



Concept/Trial Development Checklist

PURPOSE: This checklist may be used as an aid for investigators when preparing a concept/trial for submission to ANZGOG. The concept/trial document should address each of the headings listed below.

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| SYNOPSIS |
| AIMS |
| Are they clearly stated? |
| BACKGROUND AND SIGNIFICANCE |
| Size of population defined? |
| Sufficient rationale to proceed? |
| Is it clinically relevant? |
| STUDY SUMMARY |
| Hypotheses: (i) are they clearly stated (ii) do they match aims and objectives? |
| Trial objectives – do they match aims? |
| Endpoints: (i) are they measurable, and (ii) are they suitable to answer trial question? |
| STUDY DESIGN AND STATISTICS |
| Phase of study? |
| Is design appropriate to address the question? |
| Are treatment arms clearly described? |
| Is the sample size justified in terms of primary endpoint? |
| Is the study likely to detect a clinically significant difference? |
| SUBJECT POPULATION |
| Inclusion and exclusion criteria – are they clearly stated and clinically relevant? |
| EFFICACY AND SAFETY |
| Are treatment modifications clearly outlined? |
| Is there a process for submission and review of adverse events? |
| FUNDING |
| Is there any financial support for the study? |

