

Title:

Investigators:

Institution(s):

Please submit the Concept Outline at least two weeks prior to the Working Party Meeting to ensure adequate time for scientific and statistical review.

Introduction:

Rationale:

Study Proposal:

Schema:

Primary Objectives:

Secondary Objectives:

Inclusion criteria:

Exclusion Criteria:

Statistical Analysis:

Biological Sub-study (if applicable):

Discussion Points and comments:

Does this concept require input from the Genomics Cancer Clinical Trials Initiative?

This can be organised through the Working Party or an approach can be made prior to the WP Meeting.

<http://gccti.org.au/>

Confirmation of review of current clinical trials via WHO International Clinical Trials Registry Platform:
Search portal to identify similar studies and list below. <http://apps.who.int/trialsearch/default.aspx>

References: