

## ASPIRATION

An observational cohort study to assess the clinical impact of comprehensive genomic profiling in metastatic lung cancer patients.

A subprogram within the MoST Framework protocol

**ALTG protocol number**                      ALTG 19/003

This study is a collaboration between the Australasian Lung Cancer Trials Group (ALTG), the Australian Genomic Cancer Medicine Centre (AGCMC) trading as Omico and the NHMRC Clinical Trials Centre, University of Sydney.

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**Background**                      There are an increasing number of genomic alterations in metastatic non-squamous non-small cell lung cancer (mNSCLC) that are not adequately identified by current diagnostic testing. Comprehensive genomic profiling (CGP) has the capacity to identify actionable genomic alterations missed by current testing, potentially allowing patients to access personalised treatment with emerging targeted drugs currently available or in development. The ASPIRATION study will evaluate the clinical impact of CGP on the management of mNSCLC and assess the feasibility of implementation of CGP nationally.

**Primary objective**                      1) To investigate whether routine CGP can be integrated into Australian clinical practice for mNSCLC patients by:

- a. Assessing the impact of CGP in generating actionable genomic information to personalise clinical decision making
- b. Assessing feasibility considerations, including time to receipt of CGP results to inform clinical care

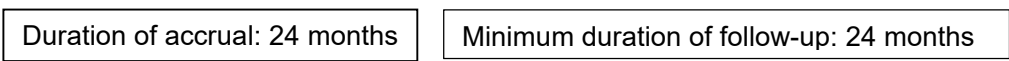
**Secondary objectives**                      To investigate the impact of CGP in the Australian context by:

- 2) Assessing the change in treatment recommendation with CGP results
- 3) Assessing the impact of CGP on clinical trial participation of investigational agent(s)
- 4) Assessing clinical outcome measures: response, PFS, OS.
- 5) Assessing healthcare resource use and costs
- 6) Assessing health-related quality of life
- 7) Assessing cost-effectiveness of CGP
- 8) Assessing collection of biospecimens for research

**Tertiary and correlative objectives**                      9) To explore potential prognostic and/or predictive tissue and circulating biomarkers of clinical outcomes and validate where possible.

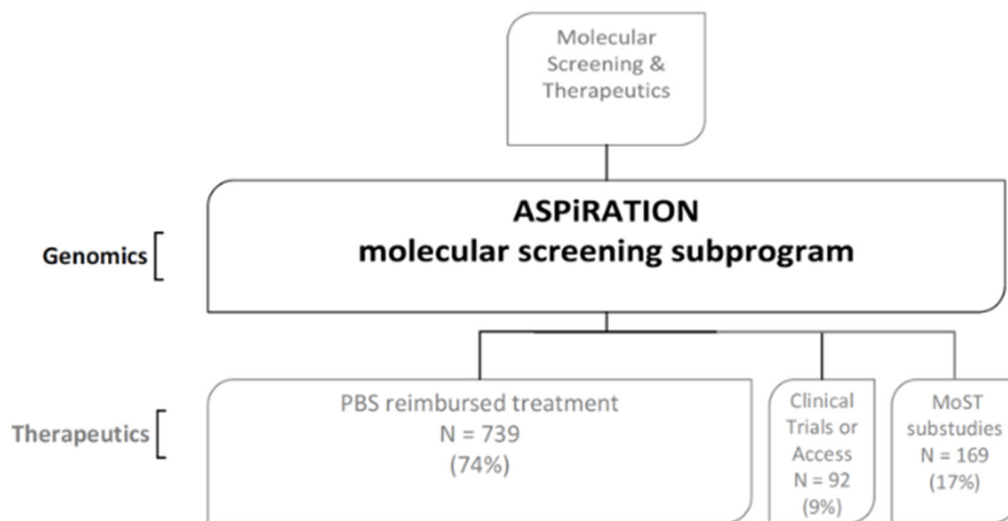
<b>Design</b>	National multi-centre prospective observational cohort study.
<b>Population</b>	Adults with newly diagnosed, pathologically confirmed metastatic non-squamous non-small cell lung cancer (mNSCLC), with sufficient and accessible tissue for molecular screening.
<b>Study procedures</b>	Concurrent with current standard of care (SoC) testing (defined as IHC/FISH/PCR for EGFR, ALK and ROS1), CGP will be performed on tumour tissue. A report containing any actionable genomic alterations and corresponding treatment recommendations will be issued to the treating clinician.
<b>Assessments</b>	All assessments are performed per standard of care. Data will be collected at baseline, then 6 monthly for at least 2 years.
<b>Statistical considerations</b>	This is a descriptive study of 1,000 patients. The primary analysis will describe the feasibility, efficiency, and utility of implementation of CGP. The study will provide important data on the ability of CGP to identify patients with targetable genomic alterations that would not be detected on SoC testing leading to personalised treatment recommendations.

**Study Schema**



**Eligibility**

- Pathologically confirmed metastatic non-squamous NSCLC
- ECOG performance status 0-1
- Sufficient tissue for molecular screening
- Signed Informed consent



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