

## ASPiRATION Referral

An observational cohort study to assess the clinical impact of comprehensive genomic profiling in metastatic lung cancer patients. The study is open to adults with newly diagnosed, pathologically confirmed mNSCLC, with sufficient and accessible tissue for molecular screening. In parallel with standard of care (SoC) testing (e.g. IHC/FISH/PCR for EGFR, ALK and ROS1), Comprehensive Genomic Profiling (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.

Date of referral: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

### Contact details

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### Face-to-face appointment

**Please send this form & histopathology report to the selected study site.**

For a list of study sites that are **open**, please visit <https://www.omico.com.au/about-us/our-network/>

- Royal North Shore Hospital, St Leonards, NSW – Dr Malinda Itchins
- Westmead Hospital, Westmead, NSW – Dr Adnan Nagrial
- Chris O'Brien Lifehouse, Camperdown, NSW – Dr Steven Kao
- St George Hospital, Kogarah, NSW – A/Prof Chee Lee
- The Canberra Hospital, Garran, ACT – Dr Geoffrey Peters
- Peter MacCallum Cancer Centre, Parkville, VIC – Prof Ben Solomon
- Austin Hospital, Heidelberg, VIC – Dr Sagun Parakh
- St Vincent's Hospital Melbourne, Fitzroy, VIC – Dr Melissa Moore
- Royal Hobart Hospital, Hobart, TAS – Dr Rebecca Tay
- Princess Alexandra Hospital, Woolloongabba, QLD – Prof Ken O'Byrne
- The Prince Charles Hospital, Chermside, QLD – Dr Brett Hughes
- Royal Adelaide Hospital, Adelaide, SA – Prof Michael Brown
- Linear Clinical Research, Nedlands, WA – Prof Michael Millward
- Royal Darwin Hospital, Tiwi, NT – Dr Michail Charakidis

### Remote consent by the Garvan Institute of Medical Research

Remote consent is available for patients who are unable to travel to a study site for molecular screening. Please note, if found eligible, patients will need to travel to a study site to access treatment on a clinical substudy.

Kind regards,

Treating clinician details:	
Surname	First name
Treating Institute	Email

I would like to **opt out** of being contacted by Roche regarding SAE reporting.

## Section 1: Patient Details

Patient Details			
Surname		First name	
Date of birth	/ /	Sex	<input type="checkbox"/> M <input type="checkbox"/> F
Address			
Phone		Email	
Next of Kin (if patient is not the preferred contact)			

Inclusion Criteria ( <i>Patients must fulfil all of the following criteria to be eligible for this study</i> ).	
<b>Aged 18 years and older.</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Newly diagnosed pathologically confirmed metastatic non-squamous non-small cell lung cancer that have not commenced systemic therapy.</b> <i>Exception: patients with a typical pattern of disease recurrence following treatment with curative intent may not require a confirmatory repeat biopsy, unless the diagnosis is unclear, such as an isolated pulmonary nodule, in which case repeat biopsy should be considered per standard practice. In exceptional circumstances, patients may be considered eligible without the need for histopathological confirmation of disease recurrence after approval from the ASPIRATION study chair or delegates;</i> <i>Mixed or other histologies:</i> <ul style="list-style-type: none"> <li>Eligible: Mixed adenosquamous where adenocarcinoma is dominant, carcinoma not otherwise specified (NOS) favouring adenocarcinoma or sarcomatoid carcinoma</li> <li>Ineligible: Mixed small cell lung cancer or Large cell neuroendocrine carcinoma</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>ECOG performance status 0 or 1.</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Sufficient and accessible tissue for molecular screening.</b> <ul style="list-style-type: none"> <li>Preferred samples are core biopsies (minimum surface area = 5mm<sup>2</sup>, ideal surface area = 25mm<sup>2</sup>)</li> <li>FNA samples (EBUS or CT guided) may be considered on a case-by case basis, provided there is sufficient tumour cell content within the FFPE / cell block.</li> <li>Archival biopsies or lung resection specimens may be suitable in some cases</li> <li>Pleural effusion samples are not considered sufficient</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Willing and able to comply with study requirements, including:</b> <i>Willing to provide signed written informed consent to participate in molecular profiling and linkage to Medicare data, and in principle willing to consider participation in a MoST sub-study if found to have an appropriate biomarker.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Life expectancy of at least 12 weeks.</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No

Exclusion Criteria ( <i>Patients will any one of the following characteristics will not be eligible for this study</i> ).	
<b>Current enrolment or participation in another clinical study with an unregistered investigational product during the last 12 months.</b> <i>Current participation in an observational (non-interventional) clinical study or during the follow-up period of an interventional study must first be discussed the study team before study enrolment.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Previous treatment for metastatic non-squamous NSCLC.</b> <ul style="list-style-type: none"> <li>For patients with symptomatic or bulky disease, where it would be detrimental to delay treatment, systemic therapy may be commenced at the clinician's discretion whilst awaiting CGP results (this is not 'previous' treatment). Patients who have had prior treatment with curable intent are eligible.</li> <li>Up to 2 cycles of systemic treatment may be permitted prior to treatment on an ASPIRATION therapeutic substudy.</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Comorbidities or conditions (e.g. psychiatric) which may contraindicate participation and/or ability to receive any systemic therapy(s).</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>History of another primary malignancy.</b> <i>The following are permitted:</i> <ul style="list-style-type: none"> <li>Malignancy treated with curative intent and with no known active disease within 2 years before consent to molecular screening and of low potential risk for recurrence</li> <li>Adequately treated non-melanoma skin cancer or lentigo maligna without evidence of disease</li> <li>Adequately treated carcinoma in situ without evidence of disease</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No

**Section 2: Cancer Diagnosis & Staging**

Diagnosis	
Date of initial diagnosis	/ /
Topography (ICD-O-3)	<input type="checkbox"/> Upper lobe, lung <input type="checkbox"/> Middle lobe, lung <input type="checkbox"/> Lower lobe, lung <input type="checkbox"/> Main bronchus <input type="checkbox"/> Overlapping lesion <input type="checkbox"/> Lung, NOS <input type="checkbox"/> Other, please specify:
Predominant Morphology	<input type="checkbox"/> Non-small cell carcinoma <input type="checkbox"/> Adenocarcinoma <input type="checkbox"/> Adenosquamous carcinoma <input type="checkbox"/> Carcinoma <input type="checkbox"/> Sarcomatoid carcinoma <input type="checkbox"/> Other, please specify:
Cancer Stage at trial entry	
Current stage of disease	<input type="checkbox"/> Metastatic <input type="checkbox"/> Recurrent, locally advanced
Was the cancer metastatic, at time of initial diagnosis?	<input type="checkbox"/> Yes <input type="checkbox"/> No      If no, date of metastatic disease diagnosis: / /
Staging methods	<input type="checkbox"/> CT <input type="checkbox"/> MRI <input type="checkbox"/> PET <input type="checkbox"/> Clinical
Are there any distant (extrathoracic) metastasis	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, site of metastasis	<input type="checkbox"/> CNS <input type="checkbox"/> Liver <input type="checkbox"/> Bone <input type="checkbox"/> Other
Have the metastasis been treated?	<input type="checkbox"/> Yes <input type="checkbox"/> No
TNM Stage at trial entry (IASLC 8 <sup>th</sup> Edition)	
T (primary tumour)	<input type="checkbox"/> Tx <input type="checkbox"/> T1 <input type="checkbox"/> T2 <input type="checkbox"/> T3 <input type="checkbox"/> T4 <input type="checkbox"/> Unknown
N (regional lymph nodes)	<input type="checkbox"/> Nx <input type="checkbox"/> N0 <input type="checkbox"/> N1 <input type="checkbox"/> N2 <input type="checkbox"/> N3 <input type="checkbox"/> Unknown
M (distant metastasis)	<input type="checkbox"/> M0 <input type="checkbox"/> M1a <input type="checkbox"/> M1b <input type="checkbox"/> M1c
Clinical Data	
ECOG	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Presentation	<input type="checkbox"/> Symptomatic <input type="checkbox"/> Asymptomatic

### Section 3: Histopathology

For each procedure (biopsy or surgery) where tumour tissue has been collected, answer the following:

Pathology 1	
Date of procedure	/ /
Type of procedure	<input type="checkbox"/> FNA <input type="checkbox"/> Core biopsy <input type="checkbox"/> Resection <input type="checkbox"/> Cytology
Reason for procedure	<input type="checkbox"/> Diagnosis <input type="checkbox"/> Molecular screening <input type="checkbox"/> Therapeutic
Site	<input type="checkbox"/> Primary site <input type="checkbox"/> Metastatic site
Standard of Care Biomarkers (EGFR, ALK, ROS1)	<input type="checkbox"/> Histopathology report attached, with biomarker results
	<input type="checkbox"/> Histopathology report attached, biomarker results pending
	<input type="checkbox"/> Histopathology attached, no standard of care biomarkers requested on this sample
Pathology 2	
Date of procedure	/ /
Type of procedure	<input type="checkbox"/> FNA <input type="checkbox"/> Core biopsy <input type="checkbox"/> Resection <input type="checkbox"/> Cytology
Reason for procedure	<input type="checkbox"/> Diagnosis <input type="checkbox"/> Molecular screening <input type="checkbox"/> Therapeutic
Site	<input type="checkbox"/> Primary site <input type="checkbox"/> Metastatic site
Standard of Care Biomarkers (EGFR, ALK, ROS1)	<input type="checkbox"/> Histopathology report attached, with biomarker results
	<input type="checkbox"/> Histopathology report attached, biomarker results pending
	<input type="checkbox"/> Histopathology attached, no standard of care biomarkers requested on this sample
Pathology 3	
Date of procedure	/ /
Type of procedure	<input type="checkbox"/> FNA <input type="checkbox"/> Core biopsy <input type="checkbox"/> Resection <input type="checkbox"/> Cytology
Reason for procedure	<input type="checkbox"/> Diagnosis <input type="checkbox"/> Molecular screening <input type="checkbox"/> Therapeutic
Site	<input type="checkbox"/> Primary site <input type="checkbox"/> Metastatic site
Standard of Care Biomarkers (EGFR, ALK, ROS1)	<input type="checkbox"/> Histopathology report attached, with biomarker results
	<input type="checkbox"/> Histopathology report attached, biomarker results pending
	<input type="checkbox"/> Histopathology attached, no standard of care biomarkers requested on this sample

## Section 4: Past History

Comorbidities – Charlson Index	Score
Myocardial infarction (history, not ECG changes only) e.g. Heart Attack	1 <input type="checkbox"/>
Congestive heart failure e.g. Heart Failure	1 <input type="checkbox"/>
Peripheral vascular disease (includes aortic aneurysm $\geq 6$ cm) e.g. Ischemia, Embolism, Thrombus Block	1 <input type="checkbox"/>
Cerebrovascular disease: CVA (Stroke) with mild or no residual deficits or TIA (Transient Ischemic Attack)	1 <input type="checkbox"/>
Dementia	1 <input type="checkbox"/>
Chronic obstructive pulmonary disease e.g. Emphysema, Chronic Bronchitis, Bronchiectasis	1 <input type="checkbox"/>
Connective tissue disease e.g. Rheumatoid Arthritis, Scleroderma	1 <input type="checkbox"/>
Peptic Ulcer Disease	1 <input type="checkbox"/>
Mild liver disease (cirrhosis without portal hypertension, includes chronic hepatitis)	1 <input type="checkbox"/>
Diabetes: no end-organ complications	1 <input type="checkbox"/>
Diabetes: end-organ complications (retinopathy, neuropathy, nephropathy, brittle)	2 <input type="checkbox"/>
Hemiplegia e.g. Stroke with paralysis	2 <input type="checkbox"/>
Mod-severe Renal Disease	2 <input type="checkbox"/>
Second tumour without metastases (exclude if >5y from diagnosis)	2 <input type="checkbox"/>
Lymphoma	2 <input type="checkbox"/>
Leukaemia (acute or chronic)	2 <input type="checkbox"/>
Mod-severe liver disease (moderate: cirrhosis with portal hypertension but without bleeding; severe: cirrhosis, portal hypertension and a history of variceal bleeding)	3 <input type="checkbox"/>
Acquired immune deficiency syndrome (not just HIV positive)	6 <input type="checkbox"/>
Second metastatic solid tumour	6 <input type="checkbox"/>
<b>TOTAL</b>	
Add one point for each decade over 50 (eg 1 point if 51-60, 2 pts if 61-70)	
<b>TOTAL</b>	

<b>Has the patient had any transplants?</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes, please specify:
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<b>Prior Cancer</b> <input type="checkbox"/> Yes <input type="checkbox"/> No			
<b>Cancer type</b>		<b>Age of diagnosis</b>	
<b>Last treatment date</b>		<b>Treating Institute</b>	
<b>Treatment</b>	<input type="checkbox"/> Surgery	<input type="checkbox"/> Systemic	<input type="checkbox"/> Radiation
<b>Family history of cancer</b> <input type="checkbox"/> Yes <input type="checkbox"/> No			
<b>Relation</b>	<b>Cancer type</b>	<b>Age of onset</b>	

<b>Prior genetic testing / conditions</b>			
Has the patient had previous genetic testing?	<input type="checkbox"/> No	<input type="checkbox"/> Yes, please specify details below	
Germline or tumour?	<input type="checkbox"/> Germline	<input type="checkbox"/> Tumour	<input type="checkbox"/> Both
Please detail genetic findings			
Is there a known familial syndrome?	<input type="checkbox"/> No	<input type="checkbox"/> Yes, please specify:	