LUMOS: Low & Intermediate Grade Glioma Umbrella Study of Molecular Guided TherapieS – Pilot Study

Dr Hao-Wen Sim on behalf of the LUMOS Investigators

COGNO
COOPERATIVE TRIALS GROUP FOR NEURO-ONCOLOGY

NHMRC Clinical Trials Centre

Trial Type and Organisation

Study Group	COGNO
Study Type	12-month pilot
Study Chair	Hui Gan
Study Sponsor	University of Sydney
Accrual target	10 in Australia
Planned Australian Sites	5

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Background

- Grade 2 and 3 gliomas (G2/3 gliomas) are the second largest group of malignant brain tumours in adults.
- Although the outcomes for G2/3 gliomas at ***progression/recurrence*** closely approach the poor outcomes for glioblastoma, there are virtually no trials for patients with relapsed G2/3 gliomas.
- LUMOS is an umbrella study specifically for patients with G2/3 gliomas to match patients with targeted therapies based on molecular testing using contemporaneous tumour tissue.

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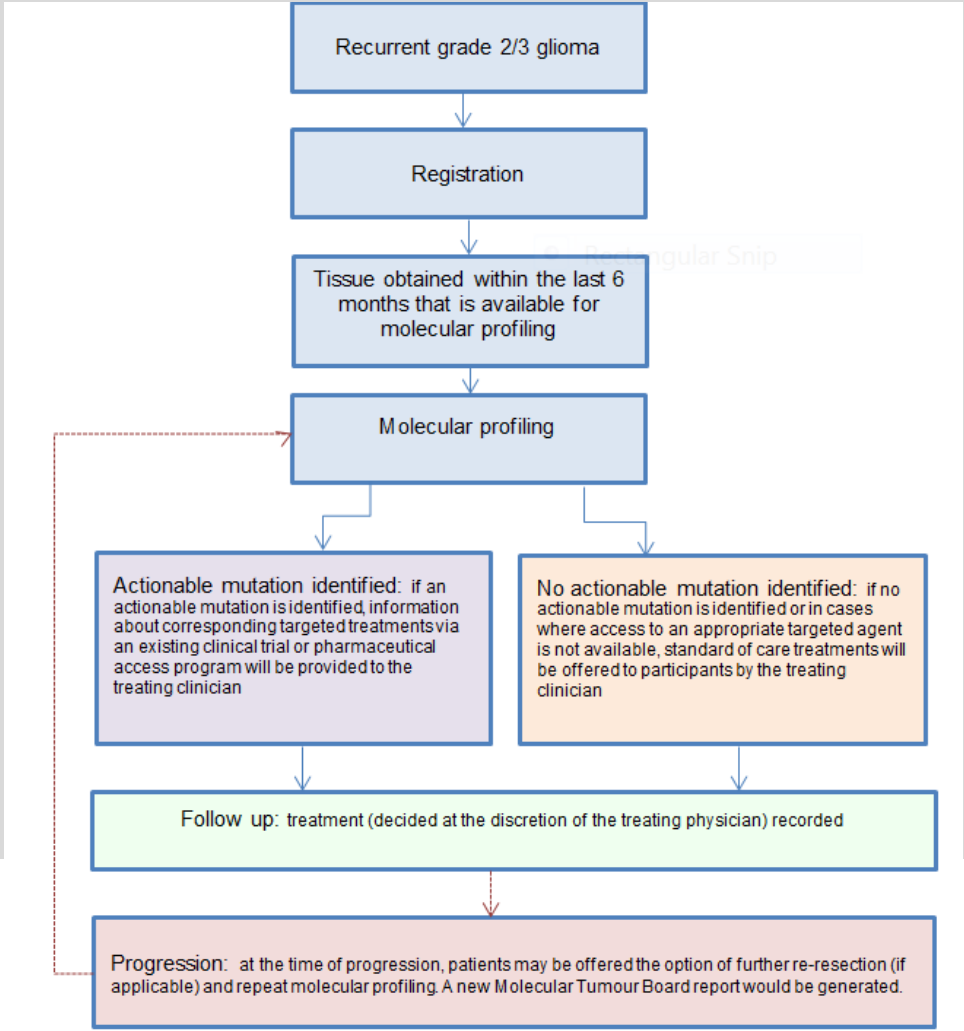
Study Design

- LUMOS is a multi-centre, pilot study enrolling a cohort of patients with **contemporaneous tissue** at the time of progression after prior radiotherapy and chemotherapy, to determine the feasibility of undertaking **molecular phenotyping** with a molecular panel to aid subsequent treatment selection.

Study Schema



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Aim

- This pilot study will generate preliminary feasibility data to support the full study. The full LUMOS study is intended to be an on-going multi-year study funded through a mixture of grants, philanthropic and industry funding. Key to attracting this funding will be providing proof-of-concept by demonstrating that this novel and ambitious concept is feasible.

Key Inclusion Criteria

- Adults, aged 18 years and older, with **histological confirmed grade 2 or 3 glioma** at initial diagnosis.
- Prior to last craniotomy and surgery, **evidence of progressive disease** as defined as evidence of new contrast-enhancing tumour and/or 25% increase in the size of the T2/FLAIR area compared to prior imaging after prior treatment with radiotherapy and chemotherapy.
- Has **available tissue** from resection for progressive disease for molecular profiling either within 6 months of study enrolment or following enrolment.
- Dose at registration must be ≤ 20mg prednisolone or ≤ 3 mg dexamethasone daily (or equivalent). Patients who are not on steroids are preferred for study participation.

Key Exclusion Criteria

- Glioma **tissue** for molecular pathology obtained ≥6 months prior to study entry
- Any intervening **systemic therapy** or **radiotherapy** between most recent imaging showing progressive disease and study enrolment
- Patients who have had **intra-surgical treatments** (e.g. oncolytic virus administration, Gliadel wafers) at their last craniotomy prior to study enrolment

Current Status & Site Activation Plan

Activity	
Australian lead HREC submission	Submitted to ethics (Sept 2019)
Sites	5 sites selected for pilot
AUS Funding	MRFF Project Grant successful for 12-month pilot
Site activation	Planned for Q1 2020

Investigators

Funder	CIs	
MRFF (AUS)	H Gan A Scott A Nowak M Khasraw B Amanuel M Buckland	R Verhaak K McDonald J Parkinson R Jeffree R De Abreu Lourenco S Yip

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