

Neuro-Oncology Disease-Oriented Team

Clinical Research Treatment Trial Flowchart



Newly Diagnosed

NRG-BN011

MGMT methylated only, IDH WT, surgery required, no biopsy,
tissue to NRG \leq 30 days from DOS; age 18-70

Randomized 1:1: RT+TMZ vs RT+TMZ+CCNU

Mechanism: Alkylating Chemotherapy

Coord: Daniel Na
Accrual: 6/8

UCI 23-198

Methylated and unmethylated; IDH WT; Biopsy ok;
Leptomeningeal disease ok***; IV medication

Randomized (2:1): NaNO₂ vs Placebo

Mechanism: A High-Capacity Oxygen Carrier/radiosensitizer

Coord: Manisha Dandekar
Accrual: 1/6

Recurrent

2nd line

UCI 24-27 (opened 12/03/24)

Enrolling in Phase I currently (Astrocytoma grade 3 and 4 only)
Phase 2 for GBM only (currently suspended)

Randomized: NMS-03305293(IP)+ TMZ 7/28 day vs 28/28 day

1st recurrence only, measurable disease required even after surgery; IDH WT;
multifocal disease allowed.

Mechanism: PARP-1 inhibitor
Coord: Daniel Na

UCI 24-39

Phase 1B

Open label: require surgical resection; IDH WT; multifocal disease
not allowed.

Mechanism: Dual Gene Therapy/immunotherapy

PRMC approved; pending IRB approval and activation

2+ lines

UCI 25-23- CAR-T therapy – immunotherapy

Phase 1

GBM 4, Astrocytoma 4, diffuse hemispheric glioma; must NTRK or
BRAF V600E, must progress on mutation directed therapy
DOT approved on 2/7/25

Open to Accrual

Low Accruing

Pending Activation/Suspended

UCI 23-67 (Screening 01 temporarily suspended)

Phase 1 Open label monotherapy

DLL3 > 50% expressed; multifocal disease allowed; any number
of recurrence ok, prior bevacizumab washout 6 months.

Mechanism: humanized IgG-like T cell engager, targets DLL3;
histologies: astrocytoma, oligodendroglioma and GBM

Coord: Daniel Na

Accrual: 1/5

ETCTN 225Ac phase I- Immunotherapy

Phase 1

Early stage in ETCTN pipeline, protocol not available, DOT
approved on 01/03/2025

Must be surgical candidates; ECOG 0-2, 1st or 2nd relapse;
measurable disease required; last RT ≥182 days; ≤2mg dexamethasone
within 2 weeks of start

ETCTN 10699

Phase 1

Awaiting final protocol, DOT approved on 03/07/2025



Newly Diagnosed

Recurrent

UCI 23-67 (Screening 01 temporarily suspended)

Open label monotherapy

Eligible histologies include:

- astrocytoma IDH mutant Grade 2-4
- oligodendroglioma IDH mutant, 1p19q co-deleted Grade 2-3
- GBM

Phase 1 (intermittently closed for analysis); DLL3 > 50% expressed; multifocal disease allowed; any number of recurrence ok, prior bevacizumab washout 6 months.

Mechanism: humanized IgG-like T cell engager, targets DLL3 cells

Coord: Daniel Na

Accrual: 1/5



Newly Diagnosed

UCI 22-83

(Temporarily suspended as of 2/28/25)

Phase III; H3 K27M mutant diffuse glioma; IP starts in adjuvant phase (2-6 weeks post RT); oral

Randomized 1:1:1: ONC201 vs Placebo

Mechanism: DRD2 dopamine receptor antagonist

Coord: Manisha Dandekar

Accrual: 2/4



Newly Diagnosed

Recurrent

A071401

Only AKT1/PIK3CA/PTEN arm open

Mechanism: blocking signaling through the AKT cellular survival pathway, leading to inhibition of cell proliferation and increased apoptosis

Coord: Daniel Na
Accrual: 2/3

ETCTN 10186 (currently no slots available)

Phase II: Nivo + Ipi + Radiosurgery

Meningioma grade II and III

Mechanism: PD-1 Inhibitor + CTLA-4 inhibitor

Coord: Manisha Dandekar

Accrual: 1/4

1st line

NRG BN013

Phase III: Single fraction Stereotactic Radiosurgery (SRS) vs Fractionated Stereotactic Radiosurgery (FSRS)

Eligible histologies within 5 years of registration:

- NSCLC m
- Melanoma
- Breast cancer
- RCC
- Gastrointestinal cancer

At least 1 and upto 8 intact brain mets; needs measurable disease: ≥ 1.0 cm and ≤ 3.0 cm; all mets must be located outside of brainstem and ≥ 5 mm from the optic nerves or optic chiasm and ≤ 3.0 cm in maximum dimension; no known leptomeningeal disease; no prior radiotherapy to the brain.

Coord: Daniel Na
Accrual: 0/5 (open in Dec 2024)

2nd line

NRG BN012

Phase III: Pre-operative Stereotactic RT vs Post-operative Stereotactic RT

1-4 lesions allowed with 1 requiring resection; prior RT or SRS to resection site is not allowed but prior SRS to other lesions allowed; known active/history of non-CNS primary cancer within 3 years (excludes germ cell tumor, SCC or lymphoma).

Mechanism: stereotactic radiosurgery

Coord: Daniel Na

Accrual: 4/6



UCI 23-199 (pending activation)

TLX101-CDx (18F-FET): radiopharmaceutical tracer
To differentiating recurrence versus pseudoprogression in gliomas
(all grades)

Dose 5mCi +/-10%; 30 days washout for experimental drugs

Coord: Sherin Mathew

SIV completed on 2/5/25; Pending activation

UCI 24-82

NF1 mut solid tumors including but not limited to nerve sheath tumors, gliomas, malignant melanoma, breast cancer and others; however, NF1 is not open currently.

Local testing; contact CRC for specific tumor types

Coord: Connie Kang
Accrual: 3/10