TriNetra™

Glio

Confidential

DATAR CANCER GENETICS

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Breaking News

TriNetra™ Glio has been awarded
Breakthrough Designation by the US FDA
making it the world's first non-invasive liquid biopsy platform
to be granted this designation for use in
Glial tumors.

What is Breakthrough Designation

The Breakthrough Device Designation is granted by the FDA for devices that demonstrate a potential for more effective diagnosis of life-threatening diseases such as cancer. The Breakthrough Devices Program intends to provide patients and healthcare providers with timely access to medical devices granted such designation by prioritized review to expedite development and assessment.

About Us

- We are a World-leading molecular oncology facility with a fully equipped laboratory, integrated process platforms, an in-house bioinformatics team, and a huge genetic database for precise and updated reporting.
- With the help of the latest technology and several years of extensive research, we offer highly effective treatment solutions to cancer patients for whom, multiple lines of treatment have failed.
- Our state-of-the-art cancer research centers in India, UK, Germany and US with a formidable team of cancer researchers, doctors, scientists, and other technologists educated and trained at top universities and institutes around the world. The facilities are NABL / ISO / CAP / CLIA / UKAS accredited.
- The company has invested more than Rs. 300 Crore to develop non-invasive blood tests for cancer screening, diagnosis, therapy guidance, and monitoring.

Problem Statement

- The diagnosis of primary brain tumors - glial malignancies (GLI-M) in individuals presenting with Intra-Cranial Space Occupying Lesions (ICSOLs) is based on Histopathological Examination (HPE) of tumor tissue obtained by an invasive brain biopsy or surgery.
- Brain biopsies can be risky, resource intensive, hard on the patient. There is always a high risk of mortality (~20%) and morbidity (~25%-30%) during a brain biopsy.
- Brain biopsies are impossible to perform in almost 40% of advanced cases.
- Almost 70% of patients with intracranial lesions who are biopsied, have benign conditions.
- Upto 20% of brain biopsies are non-diagnostic (where definitive diagnosis is impossible).

About TriNetra™ Glio

TriNetra™ Glio is indicated for patients with brain lessions - ICSOL where a biopsy is unviable due to inaccessibility of the tumor or comorbidity / refusal of the patient or the biopsy has been non-diagnostic. The indication for use will be expanded eventually to include diagnosis of all patients with brain lesions.

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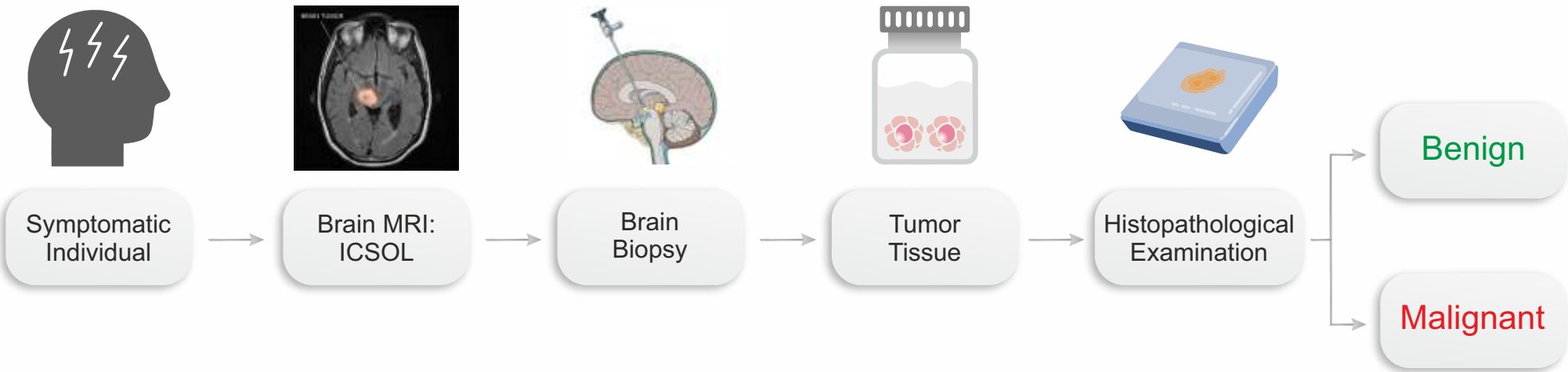
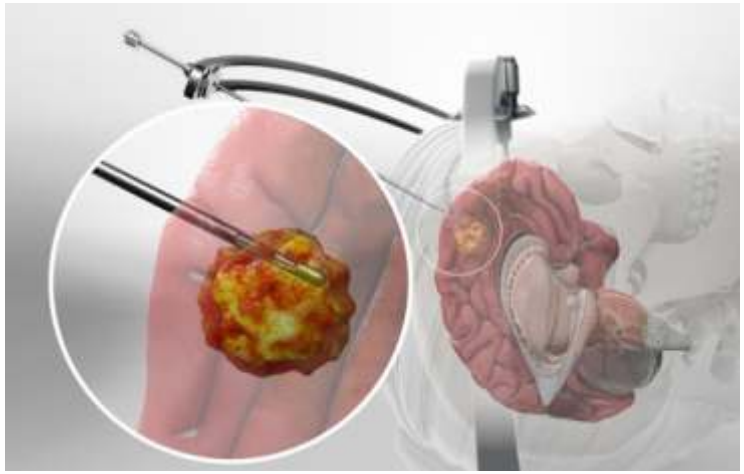
Conventional Process



- Diagnosis of glial malignancies in individuals with a radiological ICSOL is based on HPE of tumor tissue obtained after an invasive biopsy or surgical resection.
- Brain biopsies are expensive and resource intensive procedures that necessitate a visit to a tertiary care center with dedicated facilities and trained staff.

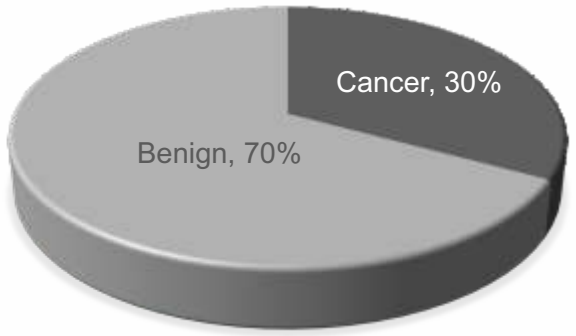
Brain Biopsies: Risks and Challenges



⚠ Intracranial Haemorrhage

⚠ Morbidity ⚠ Mortality

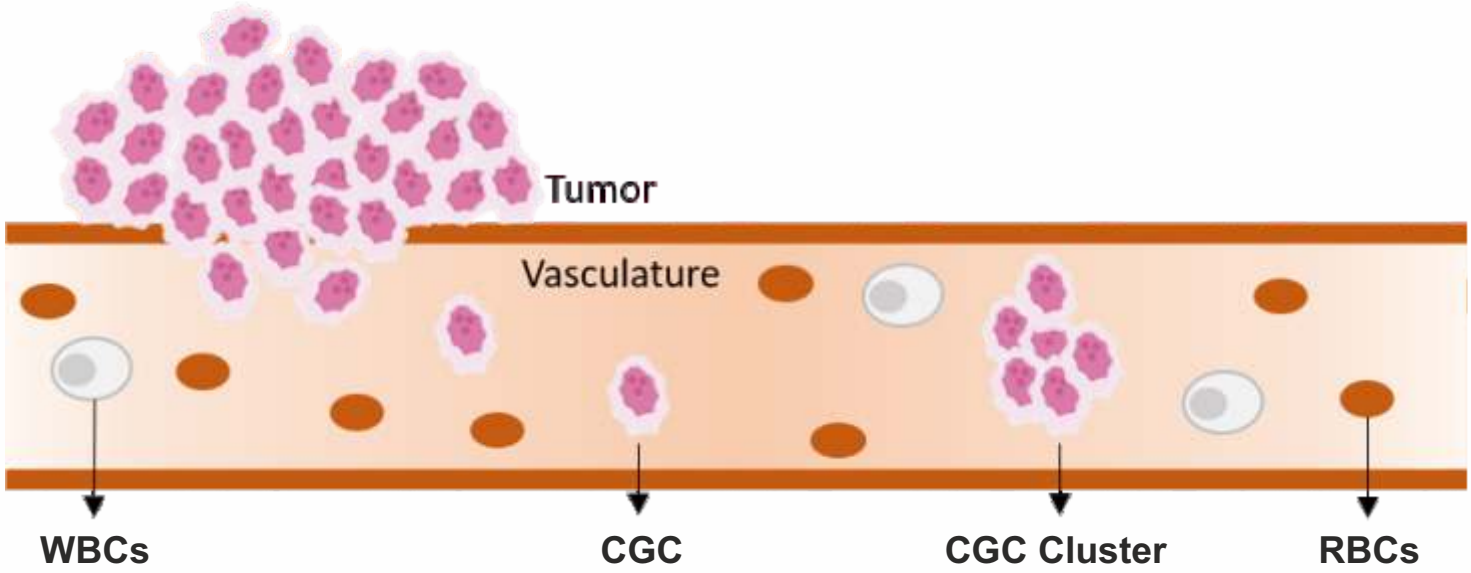
- Repeat biopsies necessitated in suspected false negative cases to disambiguate progression from pseudo-progression.
- Biopsies are often unviable owing to location of tumor in vital region of brain as well as due to patient comorbidities.
- Such incidences lead to extended time to diagnosis and time to treatment.



Two-thirds of all brain tumors are benign. However, confirmation of benign or malignant status requires an invasive biopsy. This indicates the high proportion of individuals who undergo an invasive procedure that is retrospectively deemed unnecessary.

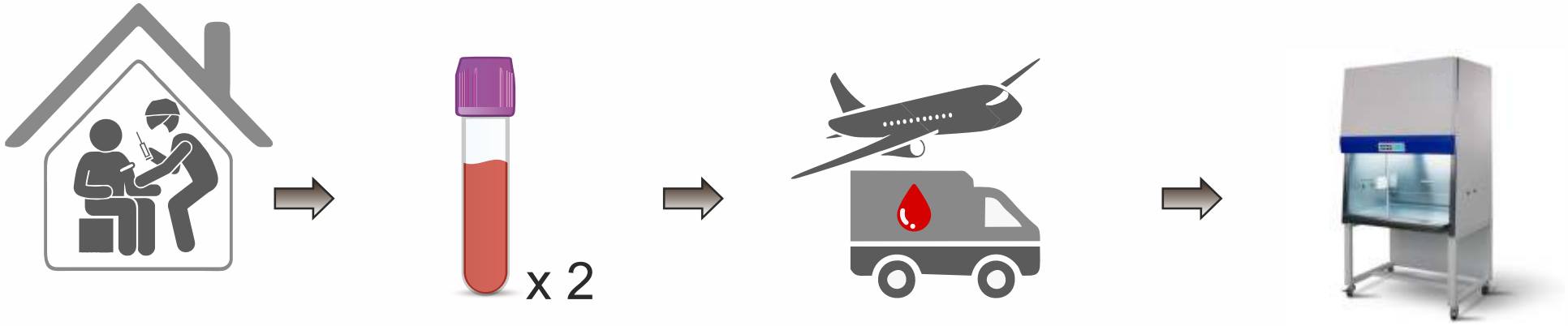
It has been reported that ~40% of all high-grade brain tumors cannot be biopsied due to inaccessibility of the tumor.

CGCs: An Ideal Analyte



- Circulating Glial Cells (CGCs) are detectable in peripheral blood of patients with Glial malignancies.
- The sensitivity of their detection is heightened by use of the proprietary enrichment media.
- Profiling of enriched tumor cells with Glial cell specific markers; GFAP and OLIG2 entrusts high specificity for Glial cell detection to this device.

Sample Collection, Storage, Transport



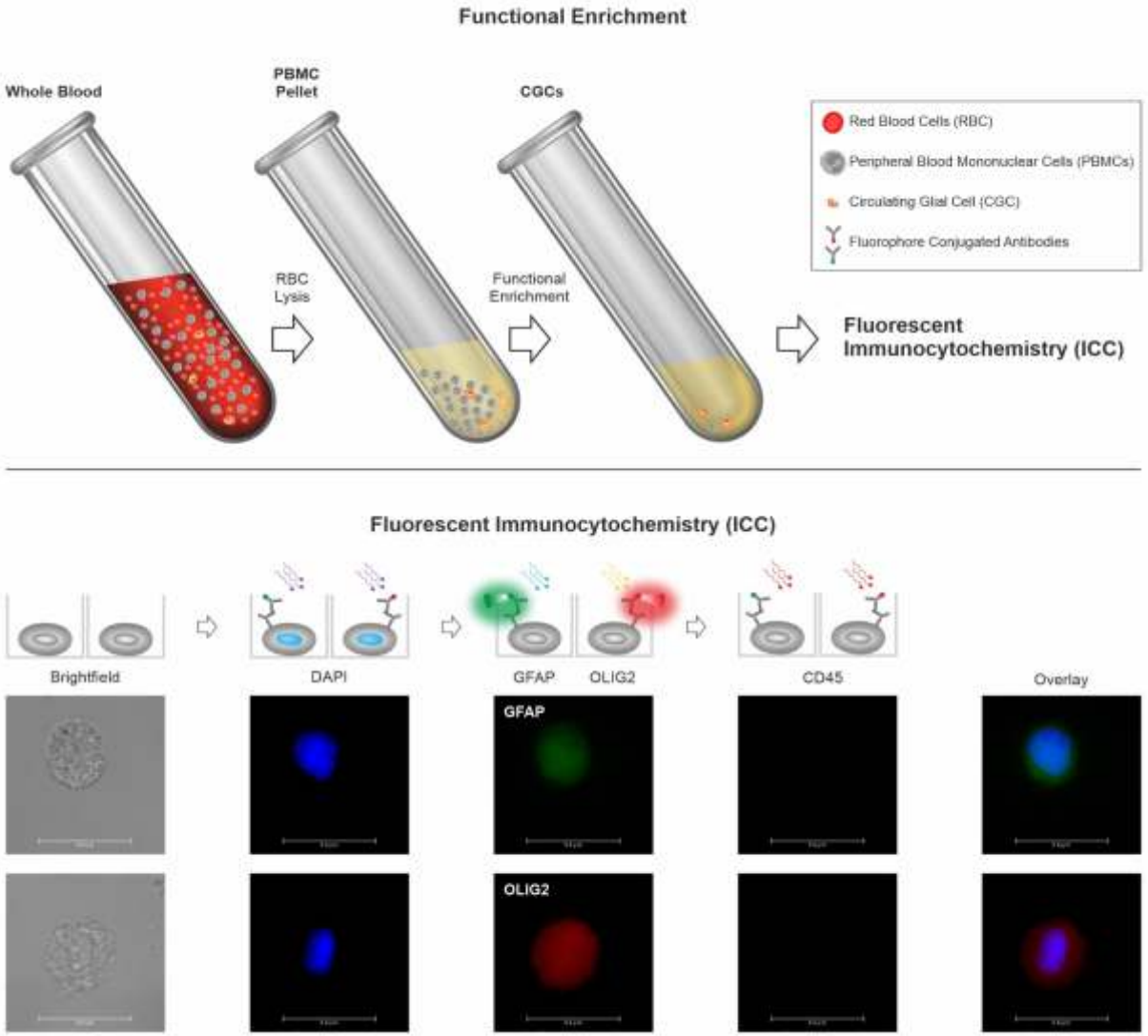
Blood Collection
from Symptomatic
Individuals

10 ml
EDTA Tubes

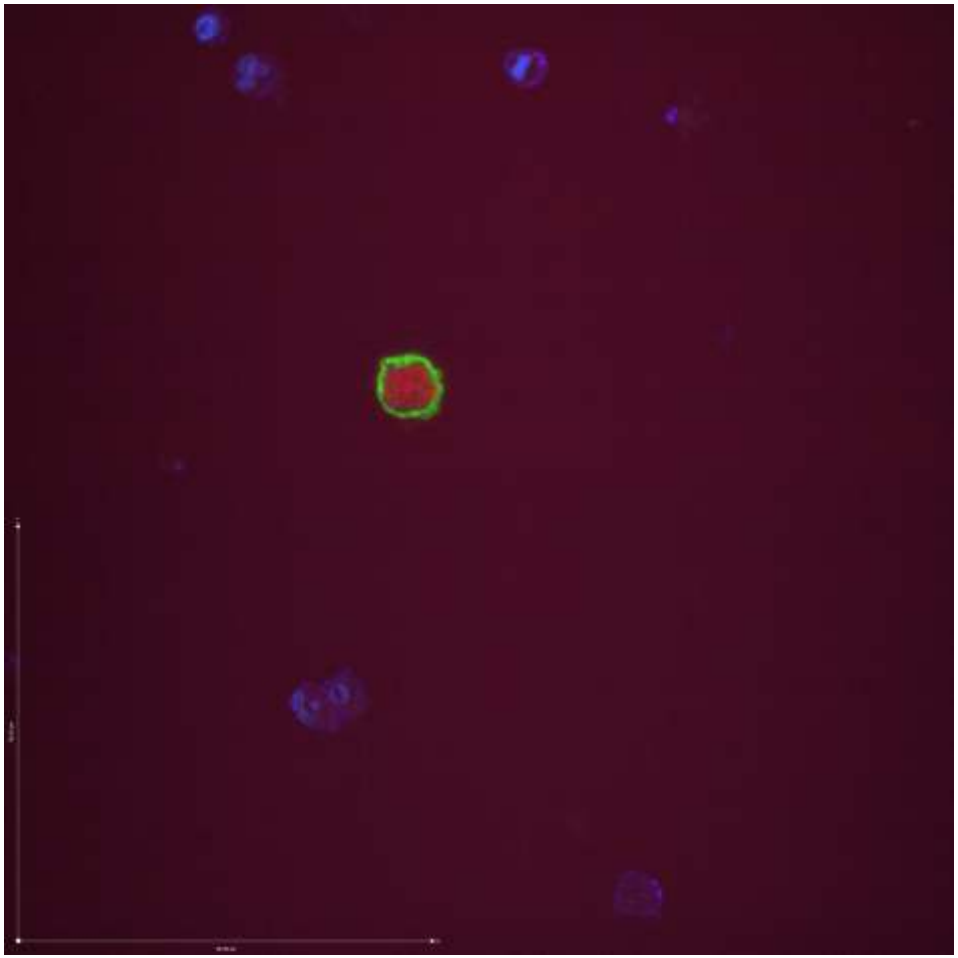
Transportation
as per DCG Protocol

Process
as per lab protocol

TriNetra™ Glio Principle



Illustrative Image of Brain Tumor Cell in Blood (1 to 2 Tumor Cell(s) Per 1 Million White Blood Cells [WBCs])



Clinical Trials

Prospective Study at The Imperial College, London

- This study was conducted by Dr. Kevin O'Neill, Consultant Neurosurgeon, Chairman of the Brain Tumour Research Campaign.
- The study enrolled surgery- and biopsy-naïve adults with ICSOLs to determine concordance between the detection of CGCs in pre-surgery / pre-biopsy blood and subsequent HPE diagnosis on tumor tissue in a blinded study.

https://doi.org/10.1093/neuonc/noac209.597

Clinical Performance of TriNetra™ Glio

	Sensitivity	Specificity	Accuracy
Case Control Study-1 (Validation Set)	100% (95% CI: 91.96% - 100%) (n = 44)	100% (95% CI: 75.29% - 100%) (n = 13)	100% (95% CI: 93.73% - 100%) (n = 57)
Case Control Study-2	100% (95%CI: 91.19% - 100%) (n = 40)	100% (95%CI: 99.33% - 100%) (n = 546)	100% (95%CI: 99.37% - 100%) (n = 586)
Prospective Study-1	100% (95%CI: 93.62% - 100% (n = 56)	100% (95%CI: 73.54% - 100%) (n = 12)	100% (95%CI: 94.72% - 100%) (n = 68)
Prospective Study-2	92.86% (95%CI: 66.13% - 99.82%) (n = 14)	100% (95%CI: 80.49% - 100%) (n = 17)	96.77% (95%CI: 83.30% - 99.92%) (n = 31)

Advantages of TriNetra™ Glio

- Primary central nervous system (CNS) tumors account for 25,000 (~1.1%) of the total ~2,300,000 annual cancer incidences and 18,000 (~3%) of the total 600,000 annual cancer-related mortalities in the US[1]. Brain tumors account for ~90% of all CNS tumors[2] and the majority (~50%) of all malignant brain tumors are Glioblastomas (GBM, Grade IV).
- Among the individuals who undergo a biopsy, 70% will be diagnosed with a benign condition. In addition, 40% of all high-grade malignancies will be potentially non-biopsiable. In around 20% of biopsied cases, the HPE findings will be non-diagnostic.
- *TriNetra™ Glio* can non-invasively provide diagnostic triaging for biopsiable cases and guidance for diagnosis in non-biopsiable cases.
- *TriNetra™ Glio* can minimize or eliminate the dependence on repeat biopsies in the non-diagnostic cases.
- The high clinical sensitivity of the test indicates a very low risk of missing any primary glial malignancy covered by the test.
- The high clinical specificity indicates virtually no risk of false positives in individuals without a primary glial malignancy.
- This can significantly reduce the financial and infra-structural burden besides alleviating the risk of pain and serious complications associated with invasive procedures.

1 Source : Globocan 2022
2 The American Society of Clinical Oncology. Brain Tumor Statistics. Accessed on 01-Jun-2022.

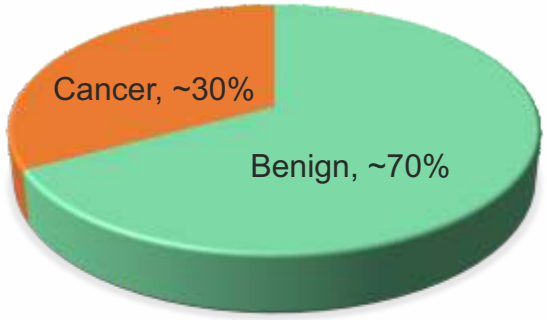
Advantages of TriNetra™ Glio

How TriNetra™ will Help in Prioritizing Patients for Brain Biopsies

Untriaged CNS Biopsies

Around 300,000 Individuals Worldwide,
(25,000 in the US,
6,000 in the UK and 31,000 in India)
will be detected with brain tumors
annually.

Two-thirds of all brain tumors are benign. However, confirmation of benign or malignant status requires an invasive biopsy. This indicates the high proportion of individuals who undergo an invasive procedure that is retrospectively deemed unnecessary.



TriNetra™ Triaged CNS Biopsies

TriNetra™ Glio can thus non-invasively provide diagnostic triaging for biopsiable cases and guidance for diagnosis in non-biopsiable cases.

DATAR CANCER GENETICS

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