BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

US FDA grants breakthrough designation for blood test to diagnose inaccessible brain tumours

January 4, 2023 | News

Datar Cancer Genetics now has three Breakthrough Designations granted by the US FDA, including liquid biopsies for breast and prostate cancer detection



Datar Cancer Genetics has announced that the US Food and Drug Administration (FDA) has granted 'Breakthrough Device Designation' for its 'TriNetra™-Glio', a blood test to help in the diagnosis of brain tumours.

This is the third test from the company to have received the Breakthrough Device Designation from the US FDA. With modern cancer research facilities in India, the UK and the US, the company's early-stage breast and prostate cancer detection tests became the first liquid biopsies to receive the Breakthrough Device Designation.

Diagnosis of brain tumours is resource-intensive, risk-prone and brain biopsies are impossible to perform in almost 40% of advanced cases. Presently, there is no blood test worldwide for the diagnosis of brain cancers, and doctors have to rely on complex surgical procedures to obtain tumor tissue for histopathological evaluation. The TriNetra™-Glio liquid biopsy is intended to detect the cells released in the blood from the brain tumor; these cells are extremely rare.

A prospective, blinded study by a research team at the Imperial College, London, showed the test to be highly accurate. The test requires 15 ml blood and is indicated for patients where a brain biopsy, although necessary, cannot be performed or has been unsuccessful.