ForPatients
by Roche

Metastatic Gastrointestinal Cancer Metastatic Lung Cancer

A Study to Evaluate the Impact of Liquid Biopsy in Participants With a Clinical Diagnosis of Advanced Cancer

Trial Status	Trial Runs In	Trial Identifier
Recruiting	4 Countries	NCT05846594 MO43989

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This is an international, prospective study to assess the impact of concomitant early use of liquid biopsy (FoundationOne® Liquid CDx) within the diagnostic pathway, compared with the standard of care diagnostic pathway, on the timing of routine cancer care in treatment-naïve participants presenting with a clinical diagnosis of advanced cancer, where the pathologic diagnosis has not yet been confirmed. Participants with one of the following two clinical presentations will be included: participants with evidence of de novo metastatic lung cancer or participants with evidence of de novo metastatic gastrointestinal cancer. Participants may have undergone different levels of diagnostic workup prior to enrollment. Participants who have not had tissue biopsy performed prior to enrollment will be classified as 'basic workup' and those who have had tissue biopsy performed prior to enrollment will be classified as 'extended workup'. During the diagnosis period, eligible participants will undergo liquid biopsy (FoundationOne® Liquid CDx assay; as per label) on blood samples. Blood samples will be tested using the FoundationOne® Liquid CDx assay at a central laboratory. In parallel, participants will undergo the standard of care diagnostic pathway, including tissue biopsy and histology workup, if not already done before enrollment, and molecular workup according to ESMO guidelines or national guidelines for each tumor type included in this study. Once a complete pathologic diagnosis has been made, the investigator (or multidisciplinary team) can complete an anti-cancer treatment recommendation assessment. Anti-cancer treatment recommendation should follow current practice and professional guidelines based on the results provided by either liquid biopsy (as per label) or tissue biopsy/ standard of care.

Hoffmann-La Roche Sponsor	**Phase 4** Phase

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Trial Identifiers

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Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	**>=18 Years**	**No**