ForPatients
by Roche

Metastatic Gastrointestinal CancerMetastatic 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
Completed	4 Countries	NCT05846594 MO43989

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

An International Prospective Study to Evaluate the Impact of Liquid Biopsy in Participants With a Clinical Diagnosis of Advanced Cancer (L1ST)

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	**N/A**

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Sponsor	Phase

NCT05846594 MO43989
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	**#18 Years**	**No**

How does the trial work? This trial is recruiting participants aged at least 18 years with clinically diagnosed metastatic lung cancer or metastatic gastrointestinal cancer that have not yet been treated. The purpose of this clinical trial is to compare how long it takes to complete a cancer diagnosis using liquid biopsy vs the current standard of care. Participants will undergo both liquid biopsy, which is a blood test used to detect cancerous tumors, and the standard route of cancer diagnosis, including a tissue biopsy.

How do I take part in this clinical trial?
To participate, you must be at least 18 years old, and have a clinical suspicion of either metastatic lung cancer or metastatic gastrointestinal cancer. It will not allowed participating if you have already received treatment for your diagnosis. You must also not have metastatic cancer that started in your brain, or if you have had another malignant cancer within 5 years before this clinical trial. If you think, you may be eligible for this clinical trial and would like to participate, please talk to your doctor. If your doctor thinks you are eligible, they may refer you to a clinical trial doctor in your area, who will give you information to help you decide if you would like to participate.

What treatment will I receive if I join this clinical trial?
You will undergo either a liquid biopsy, which will require a blood draw, or undergo tissue biopsy and imaging as part of a standard cancer diagnosis. You will not receive treatment as part of this trial, though you may receive anti-cancer treatment prescribed by your doctor as regular care if eligible.

How often will I be seen and for how long? The diagnosis period may take from 4-8 weeks. The number of required visits will be determined by the doctor. Treatment will not be included in this clinical trial.

What happens if I am unable to take part in this clinical trial? If this clinical study is not suitable for your condition, your doctor may be able to recommend other clinical trials. It will not affect access to your regular medical care. For more information about this clinical trial, please refer to forpatients.roche.com.

Inclusion Criteria:

- Participants presenting with a clinical diagnosis of advanced cancer, falling into one of the following two clinical presentations:

i) De novo metastatic lung cancer as evidenced by imaging demonstrating a lung nodule/mass and objective evidence of a metastatic process; OR, ii) De novo metastatic gastrointestinal cancer as evidenced by imaging demonstrating a metastatic process in the abdomen/pelvis

- Participants who are treatment naïve for the metastatic setting under study
- Ability to comply with the study protocol
- Participants must either:

i) Have a tissue biopsy intended/planned to confirm malignant disease and histology; OR, ii) Have a tissue biopsy already performed but pathology has not yet been finalized.

If a tissue biopsy has already been performed prior to ICF signature, then the subtyping of primary tumor may have already been assessed (i.e., for lung cancer TTF1, p40, and napsin A IHC staining may have already been performed).

Exclusion Criteria:

- Participants deemed not fit for treatment with systemic therapy
- Participants deemed not fit for tissue biopsy
- Participants with hematological neoplasm
- Participants with primary malignant neoplasm of the brain
- Participants with any previous molecular testing (NGS or other methods) e.g., all immunohistochemistry staining recommended by ESMO aiming to define the treatment decision (i.e., for lung cancer ALK, EGFR, and PD-L1 IHC staining must not have already been performed). Participants in which tissue biopsy and primary histotyping have been performed can be included in the study.
- Prior treatment for metastatic cancer with the exception of participants who have already been diagnosed and treated for cancer, other than the cancer type under study, who have no evidence of relapse
- History of malignancy within 5 years prior to screening, with the exception of the cancer under investigation in this study and malignancies with a negligible risk of metastasis or death (e.g., 5-year overall survival rate > 90%), such as adequately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, localized prostate cancer, ductal carcinoma in situ, or Stage I uterine cancer