RECRUITING

# Circulating Tumor DNA (ctDNA) for Early Treatment Response Assessment of Solid Tumors

**Information provided by** Washington University School of Medicine (Responsible Party)

Last Updated: April 4, 2022

ClinicalTrials.gov Identifier: **NCT04354064**



Study record dates

Study | No Results Posted

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## Study Overview

**Brief Summary:**
Earlier detection of disease recurrence will enable greater treatment options and has strong potential to improve patient outcomes. This project is translational and has the potential to lead to future translational research opportunities, including interventional trials in which therapeutic escalation is

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OFFICIAL TITLE

Circulating Tumor DNA (ctDNA) for Early Treatment Response Assessment of Solid Tumors

CONDITIONS

Healthy Volunteer Prostate Cancer

Head and Neck Cancer

STUDY TYPE

Observational [Patient Registry]

ENROLLME

3362

Collaborators and Investigators

Publications

More Information

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Esophageal Cancer

Show 9 more conditions

| INTERVENTION / TREATMENT | PHASE | OTHER STUDY ID NUMBERS |
|---|---|---|
| | | 201903142 |

| STUDY START (ACTUAL) | PRIMARY COMPLETION (ESTIMATED) | STUDY COMPLETION (ESTIMATED) |
|---|---|---|
| May 29, 2019 | December 31, 2025 | December 31, 2025 |

### Resource links provided by the National Library of Medicine

NIH NLM

Other U.S. FDA Resources

# Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

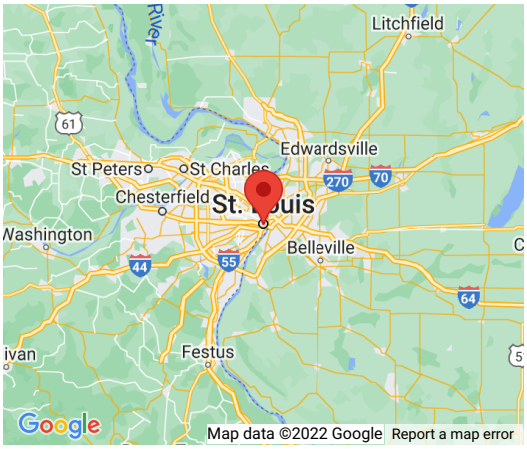
STUDY CONTACT

**Name:** Aadel Chaudhuri, M.D., Ph.D.
**Phone Number:** 314-273-2931
**Email:** aadel@wustl.edu

### United States

**Missouri Locations**

**Saint Louis, Missouri, United States, 63110**
**Recruiting**
Washington University School of Medicine
Contact: Aadel Chaudhuri, M.D., Ph.D.
314-273-2931 aadel@wustl.edu
Principal Investigator: Aadel Chaudhuri, M.D., Ph.D. Show more




# Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies.

## Eligibility Criteria

| AGES ELIGIBLE FOR STUDY | ACCEPTS HEALTHY VOLUNTEERS | SEXES ELIGIBLE FOR STUDY |
|---|---|---|
| 18 Years and older (Adult, Older Adult) | Yes | All |

SAMPLING METHOD

Non-Probability Sample

STUDY POPULATION

- This study will access data and specimens from patients who consented to specimen banks (approximately 3262 patients) There is a waiver of consent for this study regarding patient

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DESCRIPTION

Inclusion Criteria:

- Eligible healthy donors will be at least 18 years of age.

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# Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

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### How is the study designed?

DESIGN DETAILS

**Observational Model:** Cohort
**Time Perspective:** Other
**Biospecimen Retention:** Samples With DNA
**Biospeciman Description:**

- Blood and/or urine from healthy volunteers under this study

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NUMBER OF GROUPS/COHORTS

2

COHORTS AND INTERVENTIONS

| Group/Cohort |
|---|

| Group/Cohort |
| --- |
| Healthy Donor Samples<br>• Donation of blood and/or urine samples as often as bi-monthly and as many as 24 times in total<br>• These samples will be used to generate reference data to compare patient data to and/or to correct stereotypic noise. |
| Samples from Repository and Banking Studies<br>• Healthy prostate and/or blood and/or urine samples from Genitourinary Repository<br>• Tissue, blood, and/or drain fluid samples from Head and Neck Banking studies<br>• Tissue and/or blood samples from Esophageal Repository<br>• Tissue and/or blood samples from Genitourinary Repository<br>• Tissue and/or plasma from Sarcoma Tissue Bank<br>• Tissue and/or plasma from Breast Cancer Bank<br>• Tissue, plasma, and/or urine from GI Tissue and Blood Bank<br>• Tissue, blood, and/or urine from Solid Tumor Bank<br>• Tissue, blood, and/or urine from Lung Cancer Bank<br>• Tissue and/or blood from Skin Cancer Bank |

## What is the study measuring?

PRIMARY OUTCOME MEASURES

| Outcome Measure | Measure Description | Time Frame |
| --- | --- | --- |
| Freedom from progression | -Defined as RECIST 1.1 based radiographic or clinical progression, with non-progressors censored at last radiographic follow-up | Through completion of study (estimated to be 6.5 years) |

SECONDARY OUTCOME MEASURES

| Outcome Measure | Measure Description | Time Frame |
| --- | --- | --- |
| Event-free survival | -Defined as post-treatment ctDNA detection or RECIST 1.1 based radiographic progression | Through completion of study (estimated |

| Outcome Measure | Measure Description | Time Frame |
|---|---|---|
| Disease-specific survival | -Defined as death from cancer | Through completion of study (estimated to be 6.5 years) |
| Overall survival | -Defined as death from any cause | Through completion of study (estimated to be 6.5 years) |
| Pathologic complete response rate | | Through completion of study (estimated to be 6.5 years) |
| Locoregional failure | -Defined as clinical or radiographic progression within the localized tumor/treatment area or regional lymph nodes | Through completion of study (estimated to be 6.5 years) |
| Distant-metastasis-free survival | -Defined as clinical or radiographic progression outside the localized tumor/treatment area and regional lymph nodes | Through completion of study (estimated to be 6.5 years) |

# Collaborators and Investigators

This is where you will find people and organizations involved with this study.

SPONSOR

**Washington University School of Medicine**

COLLABORATORS

Roche Sequencing Solutions

The Foundation for Barnes-Jewish Hospital

National Center for Advancing Translational Science (NCATS)

Radiological Society of North America

Skandalaris

The V Foundation for Cancer Research

National Institute of General Medical Sciences (NIGMS)

INVESTIGATORS

Principal Investigator: Aadel Chaudhuri, M.D., Ph.D., Washington University School of Medicine

# Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

GENERAL PUBLICATIONS

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

# More Information

History of Changes

Expand all / Collapse all

### Terms related to this study

ADDITIONAL RELEVANT MeSH TERMS

Neoplasms
Neoplasms by Site
Digestive System Neoplasms
Digestive System Diseases
Gastrointestinal Diseases
Gastrointestinal Neoplasms
Urogenital Neoplasms

## Plan for Individual participant data (IPD)

PLAN TO SHARE INDIVIDUAL PARTICIPANT DATA (IPD)?

Yes

IPD PLAN DESCRIPTION

All of the individual participant data collected during the trial, after deidentification will be available for sharing with other researchers.

## Drug and device information, study documents, and helpful links

STUDIES A U.S. FDA-REGULATED DRUG PRODUCT

No

STUDIES A U.S. FDA-REGULATED DEVICE PRODUCT

No

HELPFUL LINKS PROVIDED BY WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

Alvin J. Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine