ASCO TAPUR
Targeted Agent and Profiling Utilization Registry Study

Dear TAPUR Participant or Caregiver,

Thank you for being part of the TAPUR Study! You belong to a large community of people across the United States who help researchers answer important questions and discover medical treatments for cancer. As someone who contributed to this study, we think it is important for you to know the results. We hope it helps you understand the study and feel proud of your key role in cancer research.

This summary describes the study results of a single treatment group that you or your loved one took part in. The following pages describe:

- What is the TAPUR Study? (page 2)
- What treatment group is this summary about? (page 3-4)
- What were the results of the study? (page 5-6)
- What were the side effects? (page 6-7)
- What happens next? (page 8)

While this summary does not go into detail about each patient, it may bring up emotions about your experience. You can choose to stop reading now or at any time. If you want to speak to someone about this summary, please contact your doctor or clinic staff.

Thank you again for your substantial contribution to cancer research.

-- The TAPUR Study Team

The Targeted Agent and Profiling Utilization Registry (TAPUR) Study is sponsored by the American Society of Clinical Oncology (ASCO).

This summary was written on **April 10, 2025,** and shares results from one group of participants that received the same treatment, referred to as a “treatment group”.

What Is the TAPUR Study?

This study is known as the Targeted Agent and Profiling Utilization Registry (TAPUR) Study. The TAPUR Study is a **precision medicine** study testing if **off-label** treatments work for different types of cancers. The study doctor uses **gene alterations** to match participants to treatment groups.

What is Off-Label Use?	A doctor can prescribe a US Food and Drug Administration (FDA)-approved medication that isn't yet approved to treat the specific type of cancer a person has. This is called using a medication "off-label." This is sometimes done when there are no remaining standard treatment options that work for patients with late-stage cancer.
What Is a Gene Alteration?	DNA is in every cell in your body. Genes are pieces of DNA that provide the blueprints for telling a cell how to work. All cancers begin when one or more genes in a cell change. These changes can come in many forms, but we refer to these changes as a "gene alteration." These alterations may cause a cell to multiply uncontrollably and become cancerous. Gene alterations can be inherited from parents, caused by exposures (such as smoking, UV radiation or viruses), or happen by chance over time.
What Is Precision Medicine?	Precision medicine uses information about the tumor and gene alterations to diagnose or treat the cancer of an individual. Doctors find this information by testing a sample of the tumor for gene alterations. This process is called genomic profiling. Genomic profiles may help doctors discover new treatment options for cancer. In the TAPUR Study, we use precision medicine to match patients to treatments called targeted therapies. Targeted therapies target specific genes, proteins, or other molecules that lead to cancer growth.
What Is the Purpose of The TAPUR Study?	The TAPUR Study looks at the effects of "off-label" medications in people with cancer that have certain gene alterations. The data from the study will help doctors and researchers figure out if FDA-approved cancer drugs will work for other cancers.

More information about this study can be found at ClinicalTrials.gov Identifier: NCT02693535.

What Treatment Group Is This Summary About?

What Did This Treatment Group Investigate?

You or your loved one took part in the treatment group that explored how sunitinib affected people with breast cancer with *FGFR1* mutation or amplification. We call this the Breast-*FGFR1*-Sunitinib treatment group.

You or your loved one received sunitinib because sunitinib has worked for other people with cancer with *FGFR1* mutation or amplification.

What Is Breast Cancer?

This summary is about breast cancer, which is cancer that began in the breast.

There are more than 120 types of cancer. Types of cancer are usually named after the organs or tissues where the cancers form. For example, lung cancer starts in the lung and kidney cancer starts in the kidney.

Your cancer was tested for a gene alteration that could be treated using a TAPUR Study medication.

What Is *FGFR1* Mutation or Amplification?

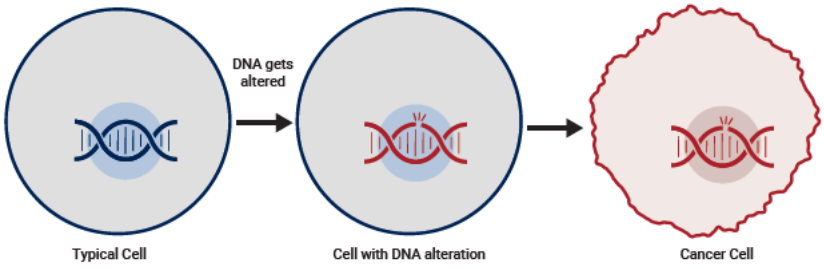
All patients in the TAPUR Study have genomic testing done on a sample of their tumor to look for changes in the cancer cells' DNA. Everyone in this treatment group had tumors with *FGFR1* mutation or amplification.

FGFR1 mutation causes the cells it affects to change. The mutation could lead to mutations in other important genes or cause cells to grow uncontrollably.

FGFR1 amplification causes the cells it affects to increase in the number of copies of a gene. Gene amplification may cause cancer cells to grow uncontrollably or become resistant to anticancer medicines.

If you have any other questions about this cell change, please speak with your doctor, clinic staff or a genetic counselor.

People with cancers other than breast cancer with *FGFR1* mutation or amplification may have responded to treatment with sunitinib which is why you or your loved one were matched to this treatment group.



What Is Sunitinib?

All patients in this treatment group received sunitinib in the form of a pill.

While your doctor may have given you other medications during treatment to help with side effects, only sunitinib was studied in the TAPUR Study.

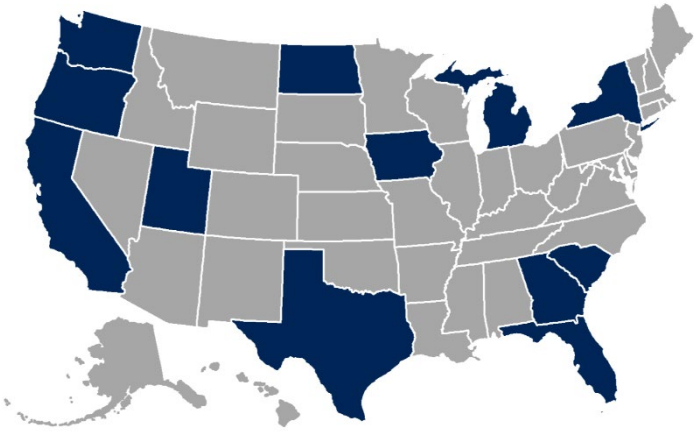
More information about side effects from sunitinib is outlined on page 6 and 7. Your doctor or clinic staff can give you more details about this medication.

While sunitinib is FDA-approved for some cancer patients with *FGFR1* mutation or amplification, at the time the TAPUR Study started, it was not approved for breast cancer.

Who Took Part in This Study?

In this treatment group, participants had at least:

- late-stage breast cancer
- a genomic profile showing a *FGFR1* mutation or amplification
- no additional standard treatment options available to them
- other blood tests or exams to determine their overall health



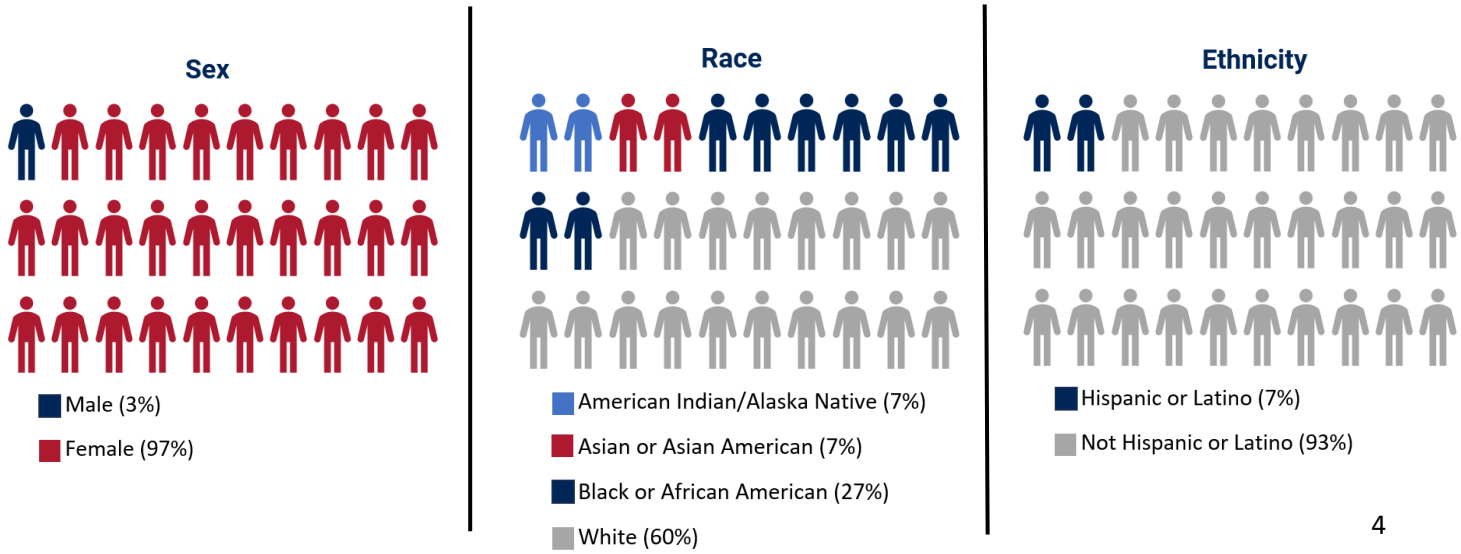
Your doctor may have had more requirements specific to your care.

Characteristics of Patients in this Treatment Group

The Breast-*FGFR1*-Sunitinib treatment group included 30 participants across 12 states. This treatment group enrolled participants between October 2016 and June 2019.

Some participants withdrew from the study for various reasons. Three participants left the study before data could be collected on their response to treatment. Results from these three participants are not included in the treatment results.

Participants in this treatment group were between 28 and 81 years old at the start of treatment. The average age of participants was 61 years old.



Treatment Group Results

What Were the Results of the Study?

During the study, you or your loved one had imaging scans done on your cancer. Each time, your doctor looked at the scan to see if the cancer had responded to treatment.

The results of this treatment group are sorted by "response categories." Each category describes if and how the cancer responded to sunitinib. If the cancer's response changed over time, the results may have changed from one response category to another.

The results below show the **best response** seen for all people that were evaluable in the study.			
Response Category	**Definition**	**Results**	**Visual**
Progressive Disease	The cancer did not stabilize or shrink. The cancer grew, spread, or got worse despite treatment with sunitinib.	21 out of 27 (78%) people had progressive disease.	
Stable Disease	The cancer did not shrink, but it did have a period of time (at least 8 weeks) when it did not grow. People continued receiving sunitinib for as long as their cancer was stable.	4 out of 27 (15%) people had stable disease for at least 16 weeks.	
Partial Response	The cancer got smaller for a period of time while a person was on treatment. This means that the tumor responded to sunitinib but didn't completely disappear. The cancer may have grown or progressed after the Partial Response.	2 out of 27 (7%) people had partial response.	
Complete Response	The cancer disappeared in response to treatment with sunitinib. There were no signs of cancer in the person's body. Although there were no signs of cancer, the cancer may have returned after the Complete Response.	0 out of 27 (0%) people had complete response.	

Disease Control

Disease control refers to all patients who had a complete response, partial response, and stable disease for at least 16 weeks.

Sunitinib controlled breast cancer in 22% of people.

This means that sunitinib controlled the cancer in 22% of people in this treatment group.

Progression-Free Survival

Progression-free survival is the length of time from the start of treatment until the first sign that the cancer has gotten worse (or progressed) or until death (whichever occurs first). We use progression-free survival to figure out how well a treatment works.

People in this treatment group had an average of 9 weeks of progression-free survival. Some people had progression-free survival as long as 16 weeks.

Overall Survival

Overall survival is the length of time that a person is still alive following the start of treatment.

People in this treatment group had an average of 34 weeks of overall survival. Some people had overall survival as long as 49 weeks.

What Do These Results Mean?

This treatment group helped us learn if breast cancer with *FGFR1* mutation or amplification responded to sunitinib.

Overall, sunitinib did not show benefits to people with breast cancer with *FGFR1* mutation or amplification based on how many people had disease control. Individual patients in the study may have had different results than the averages summarized here. If you have specific questions about your or your loved one's personal experience, please speak to your doctor or clinic staff.

What Were the Side Effects?

Common and serious side effects that occurred during the study are shared in this section.

What Is the Difference Between a Side Effect and a Serious Side Effect?

Side effects are any negative or unintended symptoms or diseases that happened during a person's time in the TAPUR Study. These effects may be related or unrelated to a treatment.

Serious side effects include any side effects that result in:

- death or life-threatening medical issues
- need for medical attention
- disability impacting a person's life on a regular basis
- birth defects

Side effects are also commonly known as "adverse events."

The TAPUR Study collects information on any side effects that needed treatment by professionals. You may have had side effects that are not listed below. Not all participants in this study had the side effects listed below.

What Side Effects Did We See in Breast-*FGFR1*-Sunitinib Treatment Group?

Side effects and serious side effects that were reported as likely related to sunitinib included:

- 7 out of 30 participants had abnormal bloodwork. This could be a sign of organ damage or infection. However, some people with abnormal bloodwork may recover on their own without any symptoms.
- 2 out of 30 participants developed high blood pressure (hypertension).
- 2 out of 30 participants developed an infection.
- 2 out of 30 participants experienced vomiting.
- 1 out of 30 participants had inflammation of the brain (encephalitis). This can cause headache, confusion, memory problems, sleepiness, hallucinations, or a stiff neck.
- 1 out of 30 participants had hand-foot syndrome. This syndrome can cause pain, swelling, numbness, tingling, or redness on the palms of the hands or soles of the feet.

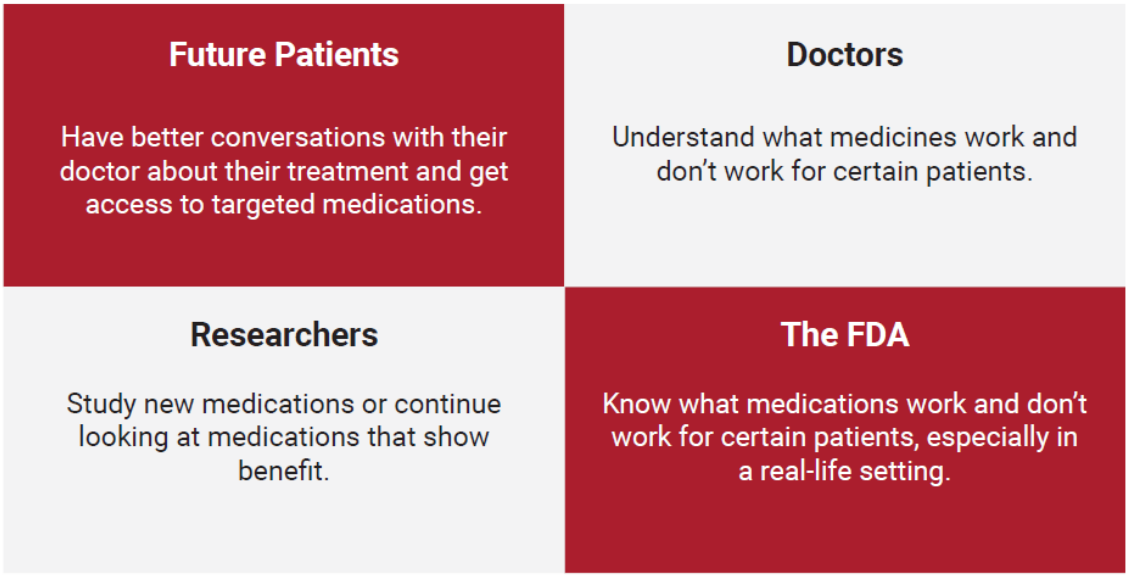
What Happens Next?

How Has This Study Helped Patients and Researchers?

This research helps future patients and families by giving us a better understanding of how sunitinib works and how it affects patients.

Even though sunitinib did not show benefits to people with breast cancer and *FGFR1* mutation or amplification, the results are still important for the cancer community.

Information from this study can help:



These findings will be shared in scientific journals and presented at scientific meetings. They will also be shared with the healthcare community to help people who care for patients make better decisions.

Findings from this study will also be shared with the pharmaceutical company that supplied the medication. The results may help them decide whether they should conduct more research on this medication.

Are There Plans for Further Studies?

The TAPUR Study does not have plans for further studies on this treatment group. The pharmaceutical company that supplied the medication or other researchers may choose to do more studies.

The TAPUR Study may also have similar studies ongoing for other treatment groups. They may share the same medication, cancer type or gene alteration as this treatment group. Results of other treatment groups will be shared separately.

Where Can I Find More Information About This Study?

To learn more about this study, you can visit:

- https://www.asco.org/tapur
- https://clinicaltrials.gov/ct2/show/NCT02693535

For more information about cancer in general:

- https://www.cancer.org/
- https://www.cancer.gov/

For general information about research studies:

- https://www.clinicaltrials.gov/ct2/about-studies/learn
- https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective

Thank you for being part of this study. ASCO sponsored this research to find better ways to treat patients with cancer. Thanks to you and your loved one, we can do that.

If you have suggestions for improving these summaries, please share them with your doctor or clinic staff.

This summary was developed by the American Society of Clinical Oncology, TAPUR Study Publications Team, with help from patient advocates, TAPUR clinical sites, participating pharmaceutical companies, ASCO MarCom and more. This summary is based on the MRCT Return of Aggregate Results Toolkit Version 3.0 developed March 13, 2017.