

Treating Hormone Sensitive Metastatic Breast Cancer:

How Real World Evidence Can Help

What is real world evidence?

- Complements the evidence learned from traditional medication studies – these are called controlled trials
 - Real world evidence is collected after a medication gets approval from the Food and Drug Administration (FDA)
- Tells us how well a medication works and how safe it is
- Helps make sure the medication works for everyone, not just the people studied in the clinical trial



Why is it important?

- Provides information for patients about treatments and their benefits
- Helps patients and doctors decide together on which treatment is best for them

Are you worried about how a certain side effect might change your ability to do what you love? **Real world evidence** can help you decide which medication best fits your needs.

Who does real world evidence help?

- Doctors and patients during conversations about choosing the right treatment
- It especially helps patients who were not well represented in the original clinical trials, including:
 - The very young or elderly
 - Those with other illnesses
 - Ethnic minorities

How does real world evidence help me?

- It may be hard for patients to access a clinical trial - many types of patients are often left out
- This information helps doctors understand if a medication works in all patients or only patients with certain characteristics
- It can tell us how a treatment will help someone just like you

Is my medication safe for me? Real world evidence:

- Expands information about breast cancer medications that the FDA has already approved
- Provides information about the safety of a medication that may have been missed as part of a clinical trial
- Helps show us how safe a medication is over a long period of time

Tell me more about metastatic hormone sensitive breast cancer

- "Metastatic" means that the cancer has traveled from where it started to another part of the body
- "Hormone sensitive" means testing shows that the cancer should respond to treatments that decrease the amount of estrogen in the body



Treatment Standards

- Your doctor uses guidelines from national oncology organizations to help choose your treatment
- One regimen is a medication that will reduce hormone levels in the body to starve the cancer (hormone therapy), given with a medication that interrupts the growth of cancer cells (CDK 4/6 inhibitor)

So, what is the real world evidence for metastatic hormone sensitive breast cancer?



- ✔ Patients who received endocrine therapy plus a CDK 4/6 inhibitor lived longer than patients who only took hormone therapy
- ✔ Patients who took endocrine therapy plus a CDK 4/6 inhibitor also had their cancer shrink or stay the same size for longer than patients who had only hormone therapy
- ✔ For most patients receiving the combination treatment, the length of survival increased by months



How safe are these medications?

All medications have side effects. Despite working the same way, there are differences among the possible options, so talk with your doctor about which one is right for you.

Your doctor will need lab work, or they may need you to have other tests done before and during treatment. The tests required and how often they are performed varies by medication.

Here are some examples of possible monitoring tests:

- Complete blood count (CBC)
- Liver function test (blood test)
- Electrolyte levels
- ECG to check heart function
- Kidney function test (blood test)

Common Side Effects	Rare Side Effects
<ul style="list-style-type: none"> • Fatigue 	<ul style="list-style-type: none"> • Change in liver function
<ul style="list-style-type: none"> • Diarrhea 	<ul style="list-style-type: none"> • Longer than normal heartbeat
<ul style="list-style-type: none"> • Low white blood cell count 	<ul style="list-style-type: none"> • Change in kidney function
<ul style="list-style-type: none"> • Low red blood cell count 	<ul style="list-style-type: none"> • Risk of blood clots
<ul style="list-style-type: none"> • Skin rash 	<ul style="list-style-type: none"> • Swelling in the lungs

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