While the primary role of the human immune system is to fight infections, major advances have been made by using medicines to trick the immune system into fighting cancer. This strategy, called ‘immunotherapy’ has shown great promise across cancer types. The first immunotherapy treatment regimen designed specifically for patients with metastatic breast cancer was approved by the FDA in 2019. This regimen, which combines immunotherapy with a single chemotherapy drug, has significant anti-cancer effects in a subset of patients with metastatic triple negative breast cancer. However, several issues still exist with immunotherapy: 1) the majority of patients with metastatic breast cancer do not benefit from existing immunotherapy treatments, and 2) immunotherapy can cause a particular set of side-effects that can be very difficult and/or dangerous for patients, caused by the immune system attacking healthy organs in the body.

Scientists are beginning to understand that the activity of the immune system (in attacking cancer, infections or our own body) is closely affected by the trillions of ‘healthy’ bacteria that normally live on the body surface. In particular, a tremendous number of these bacteria live in our intestines and colon, and form a healthy balanced system called the ‘intestinal microbiome,’ which can differ significantly from person to person depending on their diet, environment, and the medicines they take. Studies in kidney, lung, and skin cancers have recently shown that certain bacteria in the intestinal microbiome may be partially responsible for the benefits and the side-effects of immunotherapy in cancer treatment, and could be used to improve immunotherapy treatment for these cancers. However, scientists have never studied the interactions between the intestinal microbiome and the effects of immunotherapy in breast cancer.

We believe that the relationship between the immune system and the microbiome is important to cancer treatment in ways that never could have been imagined. Because of this, we are proposing the first efforts to examine the intestinal microbiome in patients with metastatic breast cancer. Specifically, we will analyze stool samples from patients before they begin immunotherapy treatment, and try to identify the specific bacteria that are associated the anti-cancer effects of immunotherapy, as well as the side-effects. The goal of this study is to lay a groundwork that will one day allow for us to expand the benefits of immunotherapy to more patients with metastatic breast cancer by giving special bacterial supplements or ‘pro-biotics’ to patients before they begin immunotherapy treatment. We may also learn about ways to selectively eradicate ‘bad’ bacteria that interfere with immunotherapy treatment. Lastly, we could identify those patients with metastatic breast cancer who are at risk for the side-effects of immunotherapy, and try to prevent these side-effects from ever occurring.