COFACTOR genomics

# JOIN US IN CLOSING THE PRECISION MEDICINE GAP

## Collaborate with Cofactor on a Clinical Study to Build Multidimensional RNA Diagnostics.

### Get In Touch

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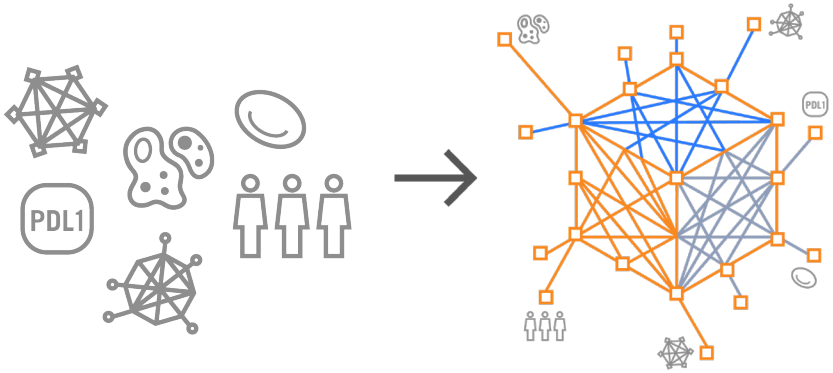
### Who We Are

Disease is complex. We're building tools to better characterize diseases like cancer using RNA and machine-learning. By better understanding why a particular set of patients see success with certain treatments, we can help match patients to effective therapies. Cofactor is leading the charge to move RNA diagnostics into the clinic, advance precision medicine, and contribute to improved patient outcomes.

### Predictive Immune Modeling

We're taking a new approach to diagnostics, by building RNA models to predict therapy response using Multidimensional Biomarkers.




Old World:
Single-Analyte

New World:
Multidimensional Model

CURRENTLY RECRUITING:

# Oncology Biospecimen Collection (HNSCC)

## Brief Study Description

The study is designed to evaluate the performance of a novel assay to predict outcomes for subjects being treated with immunotherapies for Head and Neck Squamous Cell Carcinoma (HNSCC).

## Background/Introduction

We seek to collect solid tumor tissue from patients that meet the criteria described below to better understand the molecular signals that could accurately predict response, prior to immunotherapy treatment. To accomplish this, we require the samples to have some specific criteria, described below. Many of the inclusion and exclusion criteria are modeled after the KEYNOTE studies in each disease area, as these studies have been accepted as appropriately homogenous patient populations for analysis.

A total of 180 samples is desired, with ideally an equal distribution of responders and non-responders (according to RECIST criteria), with homogenous demographic data, and other pathological features (such as HPV status) balanced, as feasible. Samples may come from multiple clinical sites.

## Inclusion/Exclusion Criteria

### INCLUSION CRITERIA

- Patients must have a confirmed diagnosis of HNSCC. Patients must have received or will receive at least one dose of immunotherapy (pembrolizumab, nivolumab, durvalumab) for the treatment of their cancer.
- Patients with sufficient tissue available to fulfill the specimen requirements of the study
- Subject must have undergone, or will undergo, medical imaging (e.g. CT or MRI) of the tumor prior to treatment with pembrolizumab, nivolumab, or durvalumab.

### EXCLUSION CRITERIA

- Patients who did not have squamous cell carcinoma (other histologies).

## Important Sample Requirements

- Samples must have been collected pre-immunotherapy treatment
- Samples must have robust demographic and pathologic data
- Samples must have clinical outcomes/follow-up data over a minimum of 2 months REQUIRED (ideally 6 months or greater) including pre- and post-treatment imaging data

## Specimen Requirements (Preference to Keep Tissue Type Consistent)

5 unstained, slide-mounted sections from the same block as the samples below, provided for histology and one of the following options:

**OPTION A** - Preferred: Unmounted Sections or Fresh Tissue

When feasible, two FFPE sections (10 µm thickness) taken sequentially from an FFPE block are cut and stored in separate tubes, clearly labeled as replicates, for each patient.

**OPTION B** - Acceptable: Slide-mounted Sections

Two FFPE slides (10 µm thickness), individually labeled as replicates, for each patient.

**OPTION C** - Acceptable: Full FFPE blocks

If required or preferred by the vendor, full FFPE blocks will be accepted.

*If 10 µm sections are unavailable, any combination that yields a total of 20 µm thickness is acceptable (for example, four 5 µm sections).*

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