

# **PROACT: PROactive evaluation of function to Avoid CardioToxicity**

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## **Study Purpose**

This study is intended to evaluate a new more in-depth and higher resolution cardiac MRI, MyoStrain<sup>®</sup>, to transform the early detection of cardiac damage that can occur frequently as a result of cancer chemotherapy. By detecting cardiac damage early, cardiologists can provide optimal cardio-protection and allow continued use of life-saving cancer treatment for patients.

## **Study Design**

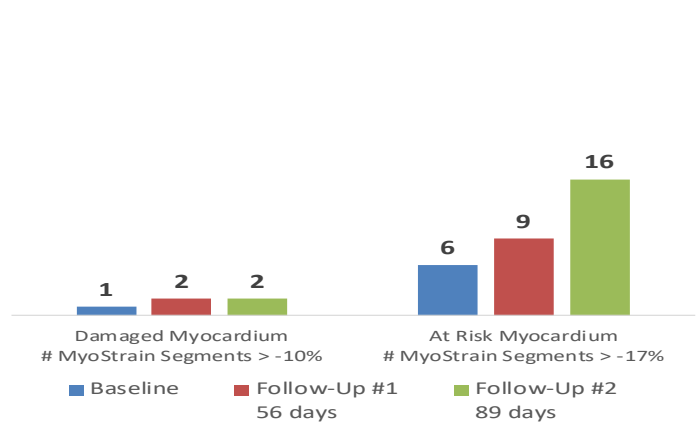
This is a prospective, multi-center, open label, randomized study. The study will enroll patients who exhibit asymptomatic cardiac dysfunction at baseline as determined by MyoStrain<sup>®</sup> evaluation.

Breast cancer, lymphoma, lung cancer, and sarcoma patients scheduled to receive chemotherapy or radiation will be screened for study participation. Consenting patients meeting all inclusion/exclusion criteria will be enrolled into the PROACT study. Once subjects are stratified to a *High Risk* Group by imaging, they will be randomized 1:1 between the MyoStrain<sup>®</sup> guided treatment arm and the standard care observational arm. Patients in both randomized study arms will be followed with MyoStrain<sup>®</sup> testing at baseline, 1, 3, 6, 12, 24 and 36 months but the cardiologist will only see the enhanced data in the MyoStrain<sup>®</sup> arm. The other half of the study will provide only the standard of care cardiac measurements to the cardiologists.

The primary objectives of this study are:

1. to robustly quantify myocardial function in patients scheduled to receive cancer treatment
2. to determine the ability of MyoStrain<sup>®</sup> testing to detect subclinical cardiac damage compared to standard cardiac imaging
3. to determine the impact of MyoStrain<sup>®</sup> imaging on medical management of cardiac damage through early detection of *High Risk* patients

**MyoStrain Test of Segmental Dysfunction**  
*Damaged vs At Risk Myocardium*



## **Expected Duration**

Based on an enrollment of 102 eligible patients who demonstrate *High Risk* of cardiotoxic effects during cardio-oncology treatment due to observed segmental dysfunction on baseline MyoStrain<sup>®</sup> evaluation, it is anticipated that all subjects will be enrolled within 12 months after study initiation. The study will end when the last enrolled subject completes the 36-month follow-up, data is analyzed and reports are written. Therefore, study duration is anticipated to be approximately 54 months.

## **Anticipated Outcome**

The imaging method for detecting cardiac damage is antiquated and insensitive. Unfortunately, cardiac damage is usually detected many months or years after it occurs with current techniques. The PROACT study will utilize the most comprehensive and accurate MRI imaging available to allow cardiologists to detect cardiac damage at its earliest point and inform the clinicians when to initiate cardioprotective therapy in high risk patients undergoing cancer therapy. The idea of preserving cardiac function would allow more patients to get the most innovative and effective treatment for their cancer.