Clinical Trials

BRAIN
No studies open to accrual at this time.

BREAST

High Risk Hormone Receptor –Positive /HER2 Negative
ID Number: S1207  Principal Investigator: Dr. Hassan Tahsildar
Title: A Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer. e3 Breast Cancer Study- evaluating everolimus with endocrine therapy
Phase: III
Purpose: The purpose of this study is to compare whether the addition of one year of everolimus to standard adjuvant endocrine therapy improves invasive disease-free survival in patients with high-risk, hormone-receptor (HR) positive and HER2-negative breast cancer.

Neoadjuvant
ID Number: NSABP B-52  Principal Investigator: Dr. Hassan Tahsildar
Title: A Randomized Phase III Trial Evaluating Pathologic Complete Response rates in Patients with Hormone Receptor-Positive, HER2-Positive, Large Operable and Locally Advanced Breast Cancer Treated with Neoadjuvant Therapy of Docetaxel, Carboplatin, Trastuzumab, and Pertuzumab (TCHP) With or Without Estrogen Deprivation
Phase: III
Purpose: The purpose of this study is to determine whether the addition of estrogen deprivation to neoadjuvant therapy consisting of docetaxel, carboplatin, trastuzumab, and pertuzumab (TCHP) yields a greater rate of pathologic complete response (breast and nodes) than TCHP alone when administered to women with operable, hormone receptor-positive, HER2-positive breast cancer.
(accrual suspended effective 5/27/2015)

Advanced
ID Number: E2112  Principal Investigator: Dr. Hassan Tahsildar
Title: A Randomized Phase III Trial of Endocrine Therapy Plus Entinostat/Placebo in Postmenopausal Patients with Hormone Receptor-Positive Advanced Breast Cancer
Phase: III
Purpose: The purpose of this study is find out what effects, both good and bad, an experimental drug called entinostat has on you and your cancer, when given together with the standard hormonal drug treatment, exemestane. Exemestane is an aromatase inhibitor which is used in breast cancer patients to inhibit the growth of the breast cancer.
Clinical Trials

Metastatic
ID Number: INCB 18424-268  Principal Investigator: Dr. Hassan Tahsildar

Title: A Randomized, Double-Blind, Phase 2 Study of Ruxolitinib or Placebo in Combination With Capecitabine in Subjects With Advanced or Metastatic HER2-Negative Breast Cancer.

Phase: II

Purpose: The primary purpose of this study is to compare how long women with advanced or metastatic HER2-negative breast cancer actively take treatment without progression of disease, whether or not the disease responds to the treatment and to assess toxicities and quality of life while being treated.

GASTROINTESTINAL/PANCREAS (UNRESECTABLEDISEASE)
No studies open to accrual at this time.

GENITOURINARY PROSTATE

Intermediate Risk/Gleason Score 7
ID Number: RTOG 0815  Principal Investigator: Dr. Charlie Pan

Title: A Phase III Prospective Randomized Trial Of Dose-Escalated Radiotherapy With or Without Short-Term Androgen Deprivation Therapy for Patients with Intermediate-Risk Prostate Cancer

Phase: III

Purpose: The primary objective of this study is to demonstrate an overall survival advantage for the addition of short-term (6 months) hormone therapy to dose-escalated radiation therapy for patients with intermediate-risk prostate cancer.

GYNECOLOGY
No studies open to accrual at this time.

LEUKEMIA/LYMPHOMAS

Untreated Younger Patients with Chronic Lymphocytic Leukemia
ID Number: E1912  Principal Investigator: Dr. Hassan Tahsildar

Title: A Randomized Phase III Study of Ibrutinib (PCI-32765) - based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL).

Phase: III

Purpose: The purpose of this study is to evaluate the ability of Ibrutinib-based induction therapy to prolong progression free survival (PFS) compared to standard FCR chemoimmunotherapy for younger patients with CLL.
Older Patients with Chronic Lymphocytic Leukemia
ID Number:  A041202  Principal Investigator: Dr. Hassan Tahsildar

Title: A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL)

Phase:  III

Purpose: The purpose of this study is to determine whether progression free survival is improved after therapy with bendamustine in combination with rituximab, ibrutinib alone, or ibrutinib in combination with rituximab in patients age 65 or older with previously untreated Chronic Lymphocytic Leukemia.

Diffuse B Cell Lymphoma
ID Number:  E1412  Principal Investigator:  Dr. Hassan Tahsildar

Title: Randomized Phase II Open-Label Study of Lenalidomide R-CHOP (R2CHOP) Vs RCHOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone) in Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma

Phase:  II

Purpose: The purpose of this study is to find out what effects, good and/or bad, the addition of lenalidomide to standard chemotherapy (RCHOP) has on you and your cancer. Everybody in this study will receive standard chemotherapy. In addition to standard chemotherapy randomly chosen half of the patients will receive a medication called lenalidomide. Adding lenalidomide to the standard chemotherapy RCHOP is considered experimental in diffuse large B cell lymphoma, and is not FDA approved.

(accrual suspended effective 5/22/2015)

Newly Diagnosed Symptomatic Multiple Myeloma
ID Number:  E1A11  Principal Investigator:  Dr. Hassan Tahsildar

Title: Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE)

Phase:  Phase III

Purpose: Primary Objectives are to compare the complete remission (CR) rate of BR versus BVR as induction therapy and to compare the 1-year post-induction disease-free survival (DFS) rate with rituximab plus lenalidomide to rituximab alone as continuation therapy.

LUNG
No studies open to accrual at this time.
Clinical Trials

MELANOMA

Unresectable Stage III/IV

ID Number: E3612    Principal Investigator: Dr. Hassan Tahsildar

Title:  A Randomized Phase II Trial of Ipilimumab with or without Bevacizumab in Patients with Unresectable Stage III or Stage IV Melanoma

Phase:  Phase II

Purpose:  The purpose of this study is to compare the good and bad effects of using the study drug called ipilimumab either alone or in combination with the study drug called bevacizumab. Ipilimumab is approved by the FDA at a dose of 3 mg/kg for a total of 4 doses given 3 weeks apart for metastatic melanoma that is not amenable to surgical resection. Bevacizumab is not approved by the FDA to treat melanoma, and is an experimental treatment.