FRHS CLINICAL TRIALS

Frederick Regional Health System (FRHS) is proud to provide a wide range of clinical trials.
Patients treated in clinical trials gain access to therapies for their diagnosis, which would otherwise be unavailable.
Patients are able to receive their study treatments conveniently within the FRHS Regional Cancer Therapy Center.

For more information about the clinical trials available at FRHS,
Please call: (301) 668-7043 or e-mail: HDIMAGGIO@fmh.org

Open trials are as follows:

BREAST:

NCT02032823	B-55	Olaparib as Adjuvant Treatment in Patients with Germline BRCA Mutated High Risk HER 2 Negative Primary Breast Cancer (OlympiA)
NCT02488967	BR003	Doxorubicin Hydrochloride and Cyclophosphamide Followed by Paclitaxel With or Without Carboplatin in Treating Patients with Triple-Negative Breast Cancer
NCT01997333	CellDex (CDX-011)	Study of Glembatumumab Vedotin (CDX-011) in Patients with Metastatic, *gpNMB* Over-Expressing, Triple Negative Breast Cancer (The Metric Study)
NCT02445391	EA1131	Platinum Based Chemotherapy or Capecitabine in Treating Patients With Residual Triple-Negative Basal-Like Breast Cancer Following Neoadjuvant Chemotherapy
NCT01674140	S1207	Hormone Therapy With or Without Everolimus in Treating Patients with Breast Cancer
NCT02513394	B57	PALbociclib CoLlaborative Adjuvant Study: A Randomized Phase III Trial of Palbociclib With Standard Adjuvant Endocrine Therapy Versus Standard Adjuvant Endocrine Therapy Alone for Hormone Receptor Positive (HR+)/ Human Epidermal Growth Factor Receptor 2 (HER2- Negative) Early Breast Cancer (PALLAS)

OVARIAN:

NCT03025867		Expanded Access Protocol For Niraparib in Patients With Recurrent Ovarian Cancer

LUNG:

NCT02154490 **S1400** Biomarker-Targeted Second- Line Therapy in Treating Patients With Recurrent Stage IIIB-IV Squamous Cell Lung Cancer

NCT02486718 **GO29527** Study to Assess Safety and Efficacy of Atezolizumab (MPDL3280A) Compared to Best Supportive Care Following Chemotherapy in Patients With Lung Cancer

SOLID TUMORS or LYMPHOMA:

NCT02465060 **EAY131 (MATCH)**
NCI-MATCH: Targeted Therapy Directed by Genetic Testing in Treating Patients With Advanced Refractory solid Tumors or Lymphomas.

MELANOMA:

NCT02224781 **EA6134** Dabrafenib and Trametinib Followed by Ipilimumab and Nivolumab or Ipilimumab and Nivolumab Followed by Dabrafenib and Trametinib in treating Patients With Stage III-IV BRAFV600 Melanoma

NCT02506153 **S1404** High –Dose Recombinant Interferon Alfa-2B, Ipilimumab, or Pembrolizumab in Treating Patients with Stage III-IV High Risk Melanoma That Has Been Removed by Surgery

MULTIPLE MYELOMA:

NCT01863550 **E1A11** Bortezomib or Carfilzomib With Lenalidomide and Dexamethasone in Treating

NCT02252172 **MMY3008** Study Comparing Daratumumab, Lenalidomide, and Dexamethasone with Lenalidomide and Dexamethasone in Participants with Previously Untreated Multiple Myeloma

SUPPORTIVE CARE (BREAST):

NCT02643420 **SPECTRUM- SPI-GCF 301 (ADVANCE)**
Randomized Trial of SPI-2012 Versus Pegfilgrastim in the Management of Chemotherapy Induced Neutropenia in Breast Cancer Patients Receiving Docetaxel and Cyclophosphamide (TC)

REGISTRY Studies:

Miraca life Science Registry Study

ProMedDx Registry Study

City of Hope

Breast Cancer Studies

Triple negative breast cancer

B-55 NCT02032823

* Olaparib as Adjuvant Treatment in Patients with Germline BRCA Mutated High Risk HER 2 Negative Primary Breast Cancer (OlympiA)
* Principal Investigator: Brian O'Connor, M.D.

* This is a randomized, double- blind, placebo controlled multi-center Phase III study to assess the efficacy and safety of *Olaparib* vs placebo as Adjuvant treatment in patients with Germline BRAC 1/ 2 mutations and high risk HER2 negative primary breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy.

* For more details, this study is posted on ClinicalTrials.gov at the following web address: https://clinicaltrials.gov/ct2/show/NCT02032823?term=NCT02032823&rank=1

Breast Cancer Studies

Triple negative breast cancer

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BR003 NCT02488967

* Doxorubicin Hydrochloride and Cyclophosphamide Followed by Paclitaxel With or Without Carboplatin in Treating Patients with Triple-Negative Breast Cancer
* Principal Investigator: Brian O'Connor, M.D.

* This randomized Phase III Trial of studies how well doxorubicin hydrochloride and cyclophosphamide followed by paclitaxel with or without carboplatin work in treating patients with triple-negative breast cancer. Drugs used in chemotherapy, such as doxorubicin hydrochloride, cyclophosphamide, paclitaxel, and carboplatin, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. It is not yet known whether doxorubicin hydrochloride and cyclophosphamide is more effective when followed by paclitaxel alone or paclitaxel and carboplatin in treating triple negative breast cancer. Patients with operable node-positive or high-risk node-negative, triple negative breast cancer who have undergone either a mastectomy or lumpectomy are eligible for this trial.
* For more details, this study is posted on ClinicalTrials.gov at the following web address: https://clinicaltrials.gov/ct2/show/NCT02488967?term=NCT02488967&rank=1

Breast Cancer Studies

Metastatic breast cancer/Triple Negative

CellDex (CDX-011) NCT01997333

* Study of Glembatumumab Vedotin (CDX-011) in Patients with Metastatic, *gpNMB* Over-Expressing, Triple Negative Breast Cancer (The Metric Study)
* Principal Investigator: Brian O'Connor, M.D.

* The main purpose of this study is to see whether CDX-011 (glembatumamab Vedotin, an antibody-drug conjugate) is effective in treating patients who have advanced Triple- Negative Breast Center (TNBC; i.e. tumors lacking expression of estrogen, progesterone and HER2 receptors), and whose tumor cells make a protein called glycoprotein NMB (*gpNMB*), which CDX-011 binds to. The study will also further characterize the safety of CDX-011 treatment in the patient population.

* For more details, this study is posted on ClinicalTrials.gov at the following web address:
  https://clinicaltrials.gov/ct2/show/NCT01997333?term=NCT01997333&rank=1

Breast Cancer Studies

Neoadjuvant Therapy before Surgery
Triple Negative Breast Cancer

ECOG-ACRIN cancer research group
Reshaping the future of patient care

EA1131 NCT02445391

* Platinum Based Chemotherapy or Capecitabine in Treating Patients With Residual Triple-Negative Basal-Like Breast Cancer Following Neoadjuvant Chemotherapy
* Principal Investigator: Brian O'Connor, M.D.

* This randomized phase III trial studies how well cisplatin or carboplatin (platinum based chemotherapy) works compared to capecitabine in treating patients with remaining (residual) basal- like triple- negative breast cancer following chemotherapy after surgery (neoadjuvant). Drugs used in chemotherapy, such as cisplatin, carboplatin and capecitabine, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. It is not yet known whether cisplatin or carboplatin is more effective than capecitabine in treating patients with residual triple negative basal-like breast cancer.

* For more details, this study is posted on ClinicalTrials.gov at the following web address: https://clinicaltrials.gov/ct2/show/NCT02445391?term=NCT02445391&rank=1

Breast Cancer Studies

Hormone receptor positive breast cancer

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S1207 NCT01674140

* Hormone Therapy With or Without Everolimus in Treating Patients with Breast Cancer
* Principal Investigator: Brian O'Connor, M.D.

* Estrogen can cause the growth of breast cancer cells. Hormone therapy using *tamoxifen citrate, goserelin acetate, leuprolide acetate, anastrozole, letrozole,* and *exemestane*, may fight breast cancer by lowering the amount of estrogen the body makes. *Everolimus* may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. On this study, patients will receive an approved endocrine therapy for at least 5 years along with *Everolimous* or placebo for 1 year.

* For more details, this study is posted on ClinicalTrials.gov at the following web address: https://clinicaltrials.gov/ct2/show/NCT01674140?term=NCT01674140&rank=1

Breast Cancer Studies

Hormone receptor positive breast cancer

NRG ONCOLOGY

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B57 NCT02513394

* PALbociclib CoLlaborative Adjuvant Study: A Randomized Phase III Trial of Palbociclib With Standard Adjuvant Endocrine Therapy Versus Standard Adjuvant Endocrine Therapy Alone for Hormone Receptor Positive (HR+)/ Human Epidermal Growth Factor Receptor 2-Negative(HER2 -) Early Breast Cancer (PALLAS)
* Principal Investigator: Brian O'Connor, M.D.

* This is a prospective, two arm, international, multicenter, randomized Phase III study evaluating the addition of 2 years of palbociclib to standard adjuvant endocrine therapy for patients with HR+/HER2- early breast cancer. The purpose of the PALLAS study is to determine whether the addition of palbociclib to adjuvant endocrine therapy will improve outcomes over endocrine therapy one for HR+/HER2- early breast cancer. Assessment of a variety of correlative analysis, including evaluation of the effects of palbociclib in genomically defined tumor subgroups, is planned.
* For more details, this study is posted on ClinicalTrials.gov at the following web address: https://clinicaltrials.gov/ct2/show/NCT02513394?term=NCT02513394&rank=1

Ovarian

Recurrent Ovarian Cancer

Tesaro, Inc. (Niraparib EAP) NCT03025867

* Expanded Access Protocol For Niraparib in Patients With Recurrent Ovarian Cancer
* Principal Investigator: Mark Goldstein, M.D.
* This is an expanded access program (EAP) for eligible patients with Recurrent Ovarian Cancer. This program is designed to provide access to niraparib prior to approval by the US Food and Drug Administration (FDA). To be eligible, patient with Recurrent Ovarian Cancer following a partial response (PR) or complete response (CR) to their most recent platinum- based chemotherapy and must have experienced a PR or CR after the penultimate (next to last) platinum-based chemotherapy for at least 6 months without disease progression after this chemotherapy.
* For more details, this study is posted on ClinicalTrials.gov at the following web address: https://clinicaltrials.gov/ct2/show/NCT03025867?term=NCT03025867&rank=1

Multiple Myeloma

Newly Diagnosed Multiple Myeloma

ECOG-ACRIN cancer research group
Reshaping the future of patient care

E1A11 NCT01863550

* Bortezomib or Carfilzomib With Lenalidomide and Dexamethasone in Treating Patients With Newly Diagnosed Multiple Myeloma
* Principal Investigator: Mark Goldstein, M.D.

* This randomized phase III trial studies *bortezomib, lenalidomide*, and *dexamethasone* to see how well it works compared to *carfilzomib, lenalidomide, and dexamethasone* in treating patients with newly diagnosed multiple myeloma. *Bortezomib* and *carfilzomib* may stop the growth of cancer cells by blocking some of the enzymes needed for cell growth. Drugs used in chemotherapy such as *lenalidomide* and *dexamethasone*, work in different ways to stop the growth of cancer cell, either by killing the cells for by stopping them from dividing. Giving *bortezomib* and *carfilzomib* together with *lenalidomide* and *dexamethasone* may kill more cancer cells.

* For more details, this study is posted on ClinicalTrials.gov at the following web address:
https://clinicaltrials.gov/ct2/show/NCT01863550?term=NCT01863550&rank=1

Multiple Myeloma

Newly Diagnosed Multiple Myeloma

Janssen (MMY3008) NCT02252172

* Study Comparing Daratumumab, Lenalidomide, and Dexamethasone with Lenalidomide and Dexamethasone in Participants with Previously Untreated Multiple Myeloma
* Principal Investigator: Mark Goldstein, M.D.

* The purpose of this study is to compare the efficacy of *daratumumab* in combination with *lenalidomide* and *dexamethasone* to that of *lenalidomide* and *dexamethasone* in terms of progression–free survival (PFS) in participants with newly diagnosed multiple myeloma (a blood cancer of plasma cells) who are not candidates for high dose chemotherapy (treatment of disease, usually cancer, by chemical agents) and autologous stem cell transplant (ASCT).
* For more details, this study is posted on ClinicalTrials.gov at the following web address: https://clinicaltrials.gov/ct2/show/NCT02252172?term=NCT02252172&rank=1

Lung Cancer

Recurrent Stage IIIB-IV Squamous Cell Lung Cancer

S1400 NCT02154490

* Biomarker-Targeted Second- Line Therapy in Treating Patients With Recurrent Stage IIIB-IV Squamous Cell Lung Cancer
* Principal Investigator: Elhamy Eskander, M.D., F.A.C.P.

* This screening and multi-sub study randomized phase II/III trial will establish a method for genomic screening of similar large cancer populations followed by assigning and accruing simultaneously to a multi-sub–study "Master Protocol". The type of cancer trait (biomarker) will determine to which sub-study, within this protocol, a participant will be assigned to compare new targeted cancer therapy, designed to block the growth and spread of cancer, or combinations to standard of care therapy with the ultimate goal of being able to approve new targeted therapies in this setting. In addition, the protocol includes a "non-match" sub-study which will include all screened patients not eligible for any of the biomarker-driven sub-studies. This sub-study will compare a non-match therapy to standard of care also with goal of approval.

* For more details, this study is posted on ClinicalTrials.gov at the following web address: https://clinicaltrials.gov/ct2/show/NCT02154490?term=NCT02154490&rank=1

Lung Cancer

Completely resected stage 1b-IIIa non-small cell lung cancer

Hoffman-La Roche (GO29527) NCT02486718

* Study to Assess Safety and Efficacy of Atezolizumab (MPDL3280A) Compared to Best Supportive Care Following Chemotherapy in Patients With Lung Cancer
* Principal Investigator: Elhamy Eskander, M.D., F.A.C.P.

* This is a phase III, open label, randomized study to investigate the efficacy and safety of *atezolizumab* (anti-PD-L1- antibody) compared with best supportive care following adjuvant cisplatin-based chemotherapy in patients with completely resected stage 1b-IIIa non-small cell lung cancer.

* For more details, this study is posted on ClinicalTrials.gov at the following web address: https://clinicaltrials.gov/ct2/show/NCT02486718?term=NCT02486718&rank=1

NCI MATCH

Advanced Refractory solid Tumors or Lymphomas

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EAY131 NCT02465060

* NCI-MATCH: Targeted Therapy Directed by Genetic Testing in Treating Patients With Advanced Refractory solid Tumors or Lymphomas.
* Principal Investigator: Patrick Mansky, M.D.

* This phase II trial studies how well treatment that is directed by genetic testing works in patients with solid tumors or lymphomas that have progressed following at least one line of standard treatment or for which no agreed upon treatment approach exists. Genetic tests look at the unique material (genes) of patients' tumor cells. Patients with genetic abnormalities (such as mutations, amplification, or translocations) may benefit more from treatment which targets their tumor's particular genetic abnormality. Identifying these genetic abnormalities first may help doctors plan better treatment for patients with solid tumors or lymphomas.
* For more details, this study is posted on ClinicalTrials.gov at the following web address: https://clinicaltrials.gov/ct2/show/NCT02465060?term=NCT02465060&rank=1

Melanoma

Patients With Stage III-IV BRAFV600 Melanoma

ECOG-ACRIN cancer research group
Reshaping the future of patient care

EA6134 NCT02224781

* Dabrafenib and Trametinib Followed by Ipilimumab and Nivolumab or Ipilimumab and Nivolumab Followed by Dabrafenib and Trametinib in treating Patients With Stage III-IV BRAFV600 Melanoma
* Principal Investigator: Mark Goldstein, M.D.
* This randomized phase III trial studies how well initial treatment with ipilimumab and nivolumab followed by dabrafenib and trametinib works and compares it to initial treatment with dabrafenib and trametinib followed by ipilimumab and nivolumab in treating patients with stage III-IV melanoma that contains a mutation known as v-raf murine sarcoma viral oncogene homolog B V600 (BRAFV600) and cannot be removed by surgery. Ipilimumab and nivolumab may block tumor growth by targeting certain cells. Dabrafenib and trametinib may block tumor growth by targeting the BRAFV600 gene. It is not yet known whether treating patients with ipilimumab and nivolumab followed by dabrafenib and trametinib is more effective than treatment patients with dabrafenib and trametinib followed by ipilimumab and nivolumab.
* For more details, this study is posted on ClinicalTrials.gov at the following web address: https://clinicaltrials.gov/ct2/show/NCT02224781?term=NCT02224781&rank=1

Melanoma

Treating patients With Stage III-IV High Risk Melanoma That Has Been Removed by Surgery

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S1404 NCT02506153

* High –Dose Recombinant Interferon Alfa-2B, Ipilimumab, or Pembrolizumab in Treating patients With Stage III-IV High Risk Melanoma That Has Been Removed by Surgery
* Principal Investigator: Mark Goldstein, M.D.

* This randomized phase III trial studies how well high-dose recombinant interferon alfa-2B or ipilimumab works compared with pembrolizumab in treating patients with stage III-IV melanoma that has been removed by surgery but is likely to come back or spread. High-dose recombinant interferon alfa-2B may help shrink or slow the growth of melanoma. Monoclonal antibodies, such as ipilimumab and pembrolizumab, may block tumor growth in different ways by targeting certain cells.
* For more details, this study is posted on ClinicalTrials.gov at the following web address: https://clinicaltrials.gov/ct2/show/NCT02506153?term=NCT02506153&rank=1

Supportive Care

Management of Chemotherapy Induced Neutropenia in Breast Cancer Patients Receiving Docetaxel and Cyclophosphamide (TC)

SPECTRUM (SPI-GCF-301) *ADVANCE*

NCT02643420

* Randomized Trial of SPI-2012 Versus Pegfilgrastim in the Management of Chemotherapy Induced Neutropenia in Breast Cancer Patients Receiving Docetaxel and Cyclophosphamide (TC)
* Principal Investigator: Brian O'Connor, M.D.

* The purpose of this study is to investigate an experimental drug called SPI-2012. SPI-2012 increases the number of white blood cells in your body. The purpose of this study is to compare SPI-2012 and pegfilgrastim, while you receive chemotherapy with docetaxel and cyclophosphamide (also called TC) for early stage breast cancer.

* For more details, this study is posted on ClinicalTrials.gov at the following web address: https://clinicaltrials.gov/ct2/show/NCT02643420?term=NCT02643420&rank=1

Registry Studies

* Miraca life Science Registry Study
* If your physician orders a bone marrow biopsy, you may be eligible participate in this study.

* ProMedDx Registry Study
* If you have cancer, you can donate blood to be used for cancer research.

* City of Hope
* There are certain types of cancer that are associated with a genetic predisposition. The City of Hope molecular genetics trial is studying links between genetics environment and behaviors. This study is free of charge and open to anyone who qualifies for genetic assessment.