RESEARCH DEVELOPMENTS
at Englewood Hospital and Medical Center

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The EHMC Clinical Research Center is continuing to attract new investigators, activate innovative clinical trials, and enroll eligible subjects. Our research program is effectively expanding into new Sections and Departments, while maintaining a strong performance in our traditional areas of high research activity. This model has allowed for consistent growth over the last few years, which we expect to continue in 2015. Below are the details on just a few of our recently-activated clinical research studies:

NEW CLINICAL RESEARCH STUDIES

STROKE

"SOCRATES"
Investigators:
Drs. Aron Schwarcz and
Rikki Racela

Patients who have an ischemic stroke or transient ischemic attack (TIA) are at high risk for developing a new ischemic stroke, even when treated with aspirin, the current standard of care. This study is designed to test the hypothesis that ticagrelor (Brilinta®) is superior to aspirin in reducing the incidence of subsequent major vascular events, including stroke, myocardial infarction, and death. Subjects will receive blinded study drug (ticagrelor or aspirin) for 90 days after their initial stroke event. Subjects will then receive maintenance therapy with the Investigator's choice of standard of care drug and followed for 30 days to assess for safety and efficacy.

HEART DISEASE

"WRAP-IT"
Principal Investigator:
Dr. Grant Simons

Pacemakers and implantable cardioverter defibrillators - also known as Cardiac Implantable Electronic Devices (CIEDs) - are known to improve the quality of life and survival of patients with heart disease. However, an increased number of device indications, coupled with an older and sicker patient population, has contributed to a higher rate of CIED infection cases. This study is looking at the effectiveness of using an absorbable antibacterial envelope to reduce the incidence of CIED-related infections. Subjects who are scheduled for a routine CIED implant will be invited to participate. Eligible subjects will be randomized to either receive the additional envelope or to not receive the envelope. All subjects will be followed for a minimum of twelve months to monitor for CIED-related infection.

GERD

"Cisapride"
Principal Investigator:
Dr. Mitchell Spinnell

Cisapride was FDA-approved in 1993 for the treatment of nighttime heartburn caused by gastroespophageal reflux disease (GERD). Due to cardiac side effects, the drug was subsequently taken off the market in 2000. However, for patients with severe GERD symptoms, the risk/benefit ratio for cisapride use may still be favorable. This limited access program allows qualifying patients to consent to take cisapride under physician supervision and with sufficient cardiac monitoring. Participants will be allowed to continue on cisapride for as long as it is beneficial. Safety and efficacy data will be collected for the duration of treatment.

COLORECTAL CANCER

"Vemurafenib"
Principal Investigator:
Dr. Minaxi Jhawer

Colorectal cancer is the second leading cause of cancer death in the U.S. 10% of colorectal cancers have a mutation in the BRAF oncogene, which is a poor prognostic indicator. As patients with BRAF-mutated, metastatic disease have only a ten month median survival, new treatment options are desperately needed. This trial is evaluating vemurafenib, an investigational new kinase inhibitor that may make these BRAF-mutated tumors more responsive to chemotherapy. The objective of this study is to compare the progression-free survival of BRAF mutant metastatic colorectal cancer patients treated with standard chemotherapy plus vemurafenib vs. a control arm of standard chemotherapy alone.

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REGISTRY STUDIES

In addition to drug and device clinical trials that test experimental new treatments, EHMC is also conducting several registry studies. These research projects allow for the collection of patient data before, during, and after 'standard' procedures. The ability to study the natural course of a disease and the efficacy of currently available treatments provides the valuable information needed to continually improve patient outcomes.

"MyPlan Registry"

Principal Investigator:
Dr. Lyall Gorenstein

The MyPlan genetic test characterizes the aggressiveness of lung cancer tumors by measuring cell proliferation and growth. Patients with early stage lung cancer will be invited to participate by agreeing to have their previously collected tumor tissue submitted for free MyPlan testing. This registry study is designed to evaluate the impact of the MyPlan test results on a surgeon's decision whether or not to refer these early stage lung cancer patients to a medical oncologist. Pre-test and post-test questionnaires will be completed by the surgeon to determine if the additional tumor characterization effects a change in recommendations. Patients will be followed for three years after the test to monitor for disease progression.

"Cancer Risk Assessment Registry"

Principal Investigator:
Dr. Rosalyn Stahl

The EHMC Cancer Risk Assessment Program is a service offered to patients with a personal or family history that may put them at an increased risk of developing cancer. The program provides patient-specific risk calculations and, if appropriate, genetic testing and counseling. This registry study intends to collect and analyze the clinical data of patients seen by the program. By analyzing this information, we will be better able to understand the impact of performing a cancer risk assessment in terms of the frequency and timing of any future cancer diagnoses, subsequent treatments, and long-term outcomes. This information may have future applications in the development of clinical care protocols and recommendations.

"SCORE Registry"

Principal Investigator:
Dr. David Feigenblum

Cardiac rhythm management (CRM) devices such as pacemakers and implantable cardioverter defibrillators have been shown to improve patient outcomes. However, as with all products, these CRM devices are subject to complications or malfunctions from a variety of mechanisms, some only recognized when the product is put to clinical use. Typically, information about these 'post-market' complications is obtained from product returns and complaints. However, this passive approach relies on voluntary reporting, which is often untimely. The aim of this device registry is to take a more rigorous approach by allowing for a prospective collection of data on the long-term reliability and performance of CRM devices manufactured by St. Jude Medical.

"CONNECT Registries"

Principal Investigator:
Dr. Michael Schleider

There is a need for prospective data that documents the diagnostic and prognostic categorization of cancer patients in routine clinical practice. EHMC is participating in several registries that will provide insights into various cancer treatment regimens and sequencing and how these correspond to clinical outcomes. These studies also incorporate quality of life questionnaires at different time points throughout the standard course of cancer treatment. This patient-reported data will help to further characterize the outcomes of different therapies. Cancer registries are open at EHMC for patients with multiple myeloma (MM), chronic lymphocytic leukemia (CLL), myelodyslplastic syndrome (MDS), and acute myelogenous leukemia (AML).

www.clinicaltrials.gov

ClinicalTrials.gov is a public website that lists clinical research studies conducted in the United States and around the world. The trial Sponsor is responsible for the posting of each study, which includes a summary of the trial, including the purpose, recruitment status, and criteria for patient participation. This public posting is:

· **Required by law:** Section 801 of the Food and Drug Administration (FDA) Amendments Act mandates the registration of certain clinical trials of drugs, biological products, and medical devices subject to FDA regulations for any disease or condition.

· **Required for journal publication**: The International Committee of Medical Journal Editors (ICMJE) requires trial registration as a condition for publication of research results generated by a clinical trial.

ClinicalTrials.gov accepts all studies (1) approved by an Institutional Review Board and (2) conforming to the appropriate regulations. Both interventional and observational studies are accepted.

The EHMC Clinical Research Center has an account with clinicaltrials.gov and will assist all EHMC researchers serving as both Sponsor and Investigator for a qualifying internal study.

Please contact the EHMC Clinical Research Center at x3418 with any questions.

LEADING THE WAY

As a testament to the commitment of the investigators and the dedication of the study coordinators in the Clinical Research Center, EHMC continues to be a leading institution on many multicenter clinical trials. Our streamlined processes and expanding infrastructure allow EHMC patients early access to the next generation of drugs and devices in a closely monitored research environment. The ability to be among the first to offer these innovative treatment options is integral to the EHMC mission to provide state-of-the art patient care.

E-14-577: **ACTitouch Venous Leg Ulcer Study**. Ahead of all other sites participating in this multicenter study, Dr. Steven Elias enrolled the first subject here at EHMC on February 18, 2015.	
E-13-475: **REVEAL AF.** With the 13th EHMC subject accrued on February 20, 2015, Dr. Jay Erlebacher is now ranked as the 3rd highest enroller worldwide.	
E-14-580: **WRAP-IT Study**. This international study has 225 participating sites, and Dr. Dmitry Nemirovsky enrolled the first subject in all of New Jersey here at EHMC on March 10, 2015.	
E-14-576: **Stem Cell Therapy for Diabetic Foot Ulcers.** Dr. Jeffrey Cohen dosed the 9th subject treated across all study sites here at EHMC on March 24, 2015	

THE EHMC CLINICAL RESEARCH CENTER

The EHMC Clinical Research Center welcomes the following new members:

• Joseph Cruz, PharmD	• Ugo Paolucci, MD
• Christopher DiGiorgio, MD	• Rikki Racela, MD
• Emily Elenio	• James Regan, RPh
• Steve Fallek, MD	• Leah Sandhaus, APN
• Jimmy Gonzalez, PharmD	• Aron Schwarcz, MD
• Maxwell Janosky, MD	• Lisa Sonzogni, APN
• Raza Karimi, MD	• Daniel Walzman, MD
• Esther JeeHae (Ahn) Lee, MD	• Christine Weiselberg, DNPc
• Deidre Minihan, PharmD	• Bruce Zablow, MD

If you are interested in registering with the Clinical Research Center, please email Jamie.Ketas@ehmc.com or Renee.Lockwood@ehmc.com for information on the required documentation and training.

A LOOK BACK AT THE NUMBERS

The EHMC Clinical Research Center had another great year in 2014, continuing the increase in research activity over the previous year:

2014

INVESTIGATORS REGISTERED WITH THE CLINICAL RESEARCH CENTER = 33

RESEARCH STUDIES APPROVED = 40

RESEARCH SUBJECTS ENROLLED = 239

The data generated by this research activity directly impacts the future of patient care. We expect the contributions made by EHMC investigators and the entire Clinical Research Center team will only continue to grow in 2015.

If you are interested in learning more about the clinical research opportunities and resources available at Englewood Hospital and Medical Center, please contact the Clinical Research Center at 201.894.3418.

Jamie Ketas
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