August 2021

Newsletter

Clinical Research Advances

YaleNewHavenHealth Smilow Cancer Hospital | Yale CANCER CENTER

Dear Colleagues,

Bob Carlson, one of our many grateful patients who have benefitted from the advances available through clinical trials at Smilow Cancer Hospital, joined us at our CTO staff meeting on Friday, July 23. Bob was successfully treated on an immunotherapy clinical trial 8 years ago and continues to show no evidence of disease during his regular check-ins. His willingness to participate in the trial early on, confidence in our team, and honest recollection of his experience reminds us all why we are working so hard to bring innovative clinical trials to our patients. I look forward to inviting more patients to future staff meetings, and hope our team found Bob's participation encouraging and valuable to their daily work.

We continue to push to fill open CTO positions, including all staffing and leadership needs. A committee will convene in the coming week to review applications for the Assistant Medical Director positions for the CTO, and we have also launched the search for the CTO Administrative Director. In addition, we are diligently working to interview candidates for open positions on our DART teams. If you have staffing recommendations, please reach out directly.

Over the last month, 39 patients started treatment on clinical trials. Please continue to review the lists of open trials and eligibility criteria with your patients in mind and discuss clinical trial opportunities with your patients. We need to focus on building accrual numbers while we simultaneously look to improve our portfolio of trials.

Please reach out to me directly with suggestions, questions, or concerns. I am grateful for the entire Cancer Center and Hospital's support of our staff, and appreciate each individual's contributions to the success of our Clinical Trials program.

Roy S. Herbst, MD, PhD
Ensign Professor of Medicine
Chief of Medical Oncology
Associate Cancer Center Director for Translational Research
Acting Associate Cancer Center Director for Clinical Sciences

YaleNewHavenHealth
Smilow Cancer Hospital

Yale CANCER CENTER
A Comprehensive Cancer Center Designated by the National Cancer Institute

CLINICAL TRIALS
KNOWLEDGE • RESEARCH • ADVANCES

July DART Accrual

Brain Tumor - 5

Breast Cancer - 3

Cellular Therapies - 0

Endocrine Cancers - 0

Clinical Trial Highlights

HIC 2000027696
PI: Francine Foss, MD

A Phase 1, Open-Label, Multicenter, Dose Escalation and Cohort Expansion Study of the Safety and Efficacy of Anti-CD70 Allogeneic CRISPR-Cas9-Engineered T Cells (CTX130) in Subjects With Relapsed or Refractory T or B Cell Malignancies

This is a single-arm, open-label, multicenter, Phase 1 study evaluating the safety and efficacy of CTX130 in subjects with relapsed or refractory T or B cell

Gastrointestinal Cancers - 0

Gynecologic Oncology - 3

Head & Neck Cancers - 1

Leukemia - 3

Lymphoma - 3

Melanoma - 3

Myeloma - 0

Pediatric Hematology/Oncology - 1

Prostate and Urologic Cancers - 0

Phase I - 8

Sarcoma - 0

Therapeutic Radiology - 4

Thoracic Oncology - 5

TOTAL = 39

Welcome & Congratulations!

New Staff, Re-Hires, Promotions, and Transfers

Elsayed Elsafy, Clinical Research Assistant

Dymond Florestal, Clinical Research Coordinator

Jamal Hanley, Clinical Research Assistant

Odamesa Igbuya, Clinical Research Assistant

Julie Lecco, Clinical Research Coordinator

Saima Masood, Clinical Research Assistant

Ana Patrovic, Regulatory Assistant

Stephanie Santillo, Regulatory Assistant

Betsy Segui, Clinical Research Assistant

Shilpa Varrier, Clinical Research Coordinator

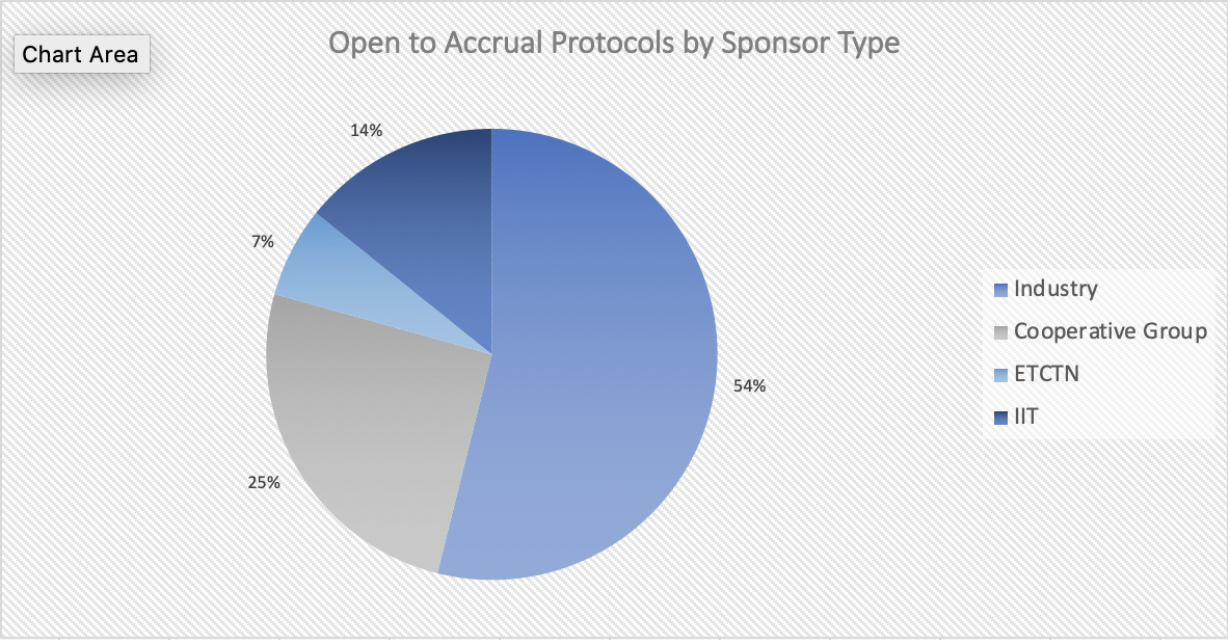
Patrick Williams, Clinical Research Assistant

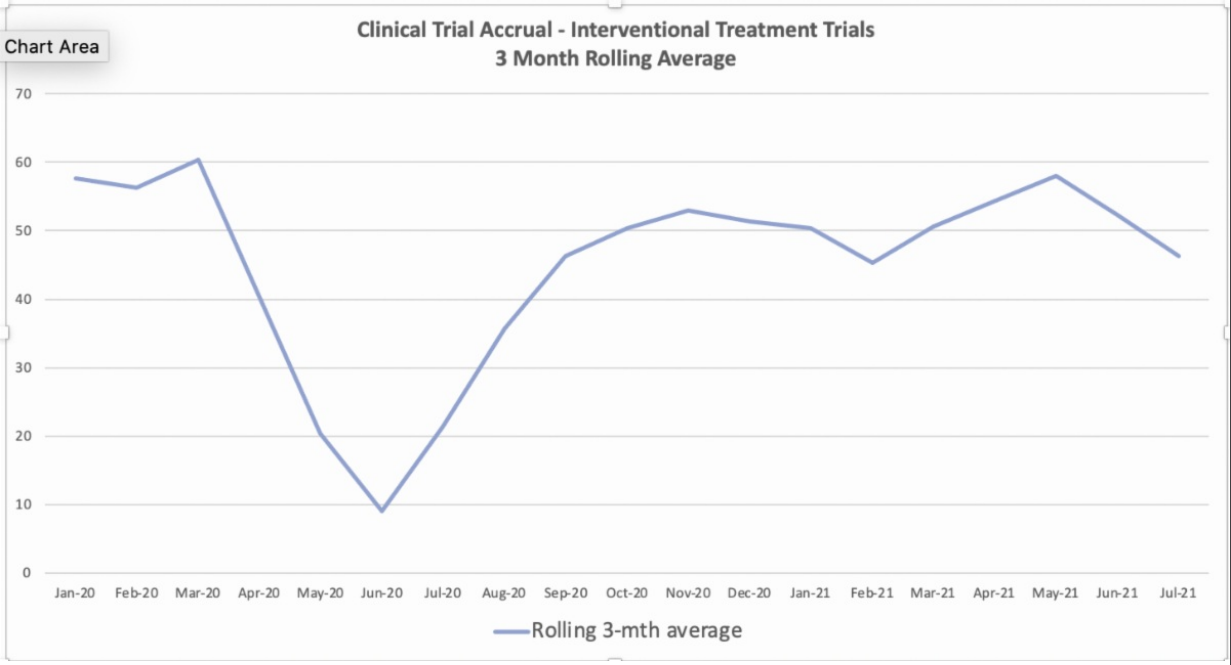
malignancies. CTX130 is an allogeneic CRISPR/Cas9 gene-edited CAR-T cell therapy targeting CD70 in development for the treatment of both solid tumors and hematologic malignancies.
Learn More

HIC 2000026830
PI: Harriet Kluger, MD

A Phase I Study of APX005M in Combination With Nivolumab and Ipilimumab in Treatment Naïve Patients With Advanced Melanoma or Renal Cell Carcinoma

This study is a Phase 1, open-label, single institution, dose escalation and dose expansion study to evaluate the efficacy, safety, and tolerability of APX005M in combination with nivolumab and ipilimumab in patients with advanced melanoma and RCC. APX005M is a potent CD40 agonist that has been designed to reverse the systemic immune suppression that typically affects cancer patients, through the activation of several mechanisms of immune functionality. CD40 is a co-stimulatory receptor that is essential for activating both innate and adaptive immune systems. Activation of CD40 initiates and amplifies a complex, multi-cellular immune response, bringing components of both immune systems to work in concert against cancer.
Learn More





Staff Spotlight: Katie Racicot

Katie Racicot is currently a Clinical

Clinical Trials in Greenwich

Our Smilow Cancer Hospital Care Center in Greenwich is now offering a collection of clinical trials for our patients treated at the Care Center. Fueled by the launch of four genitourinary trials led by Dr. Daniel Petrylak and his team, the Center now has 24 trials available in 9 different disease areas. Please reach out to Lindsey Waggoner, RN, Clinical Research Nurse.

Research Assistant on the Therapeutic Radiology Disease Team (T-Rad). She has worked in the Clinical Trials Office for the last two years and is responsible for entering data, scheduling all research visits, and communicating with all patients enrolled to research protocols on the team. During COVID, Katie also stepped up to help cover another team and has been a critical support for the CTO. She has also created multiple tools to help streamline processes for the team and improve efficiencies. Her "can do" and positive attitude toward every assignment is admired by all members of her team, her manager, the investigators, and most importantly the patients. She responds to her responsibilities with a high level of professionalism and has a keen eye for detail. The T-Rad team and CTO appreciate all Katie brings to support our patients each and every day!

Recently Opened Trials for Accrual

A Phase II Study to Evaluate the Safety and Efficacy of OQL011 on VEGFR Inhibitor-Associated Hand-Foot Skin Reaction in Cancer Patients
HIC# 2000027716
Principal Investigator: Jonathan Leventhal, MD

A Multi-center Single Arm Phase II Study to Evaluate the Safety and Efficacy of Genetically Engineered Autologous Cells Expressing Anti-CD20 and Anti-CD19 Specific Chimeric Antigen Receptor in Subjects With Relapsed and/or Refractory Diffuse Large B Cell Lymphoma
HIC# 2000028478
Principal Investigator: Iris Isufi, MD

A Randomized, Open-Label, Phase 3 Trial of Tisotumab Vedotin vs Investigator's Choice Chemotherapy in Second- or Third-Line Recurrent or Metastatic Cervical Cancer
HIC# 2000029728
Principal Investigator: Alessandro Santin, MD

A Phase 2, Multicenter Study of Autologous Tumor Infiltrating Lymphocytes (LN 144 or LN-145) in Patients With Solid Tumors
HIC# 2000023142
Principal Investigator: James Farrell, MD

A Phase 1, Open-Label, Multicenter, Dose Escalation and Cohort Expansion Study of the Safety and Efficacy of Anti-CD70 Allogeneic CRISPR-Cas9-Engineered T Cells (CTX130) in Subjects With Relapsed or Refractory T or B Cell Malignancies
HIC# 2000027696
Principal Investigator: Francine Foss, MD

A Phase I Study of APX005M in Combination With Nivolumab and Ipilimumab in Treatment Naïve Patients With Advanced Melanoma or Renal Cell Carcinoma
HIC# 2000026830
Principal Investigator: Harriet Kluger, MD

Evaluation of the TULSA-PRO MRI-Guided Transurethral Ultrasound Prostate Ablation Device in Patients With Localized Prostate Cancer: a Prospective, Single-Arm, Pivotal Clinical Study
HIC# 2000029224
Principal Investigator: Sandeep Arora, MD

Open Label, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Clinical Activity of CYH33, an Oral PI3K Inhibitor in Combination With Olaparib, an Oral PARP Inhibitor in Patients With Advanced Solid Tumors
HIC# 2000029769
Principal Investigator: Navid Hafez, MD

STAY CONNECTED