June 2021

Newsletter

Clinical Research Advances

YaleNewHavenHealth Smilow Cancer Hospital | Yale CANCER CENTER

Dear Colleagues,

Thank you for your continued commitment to our clinical research enterprise as we work together to strengthen our organization and develop the best strategies for clinical trial design, development, and activation. I recognize the impact that challenges in our Clinical Trials Office has on our clinical priorities, and appreciate everyone's ongoing support as we work together to achieve a stronger, more responsive clinical trials operations.

We are continuing with our reorganization process, while actively recruiting to fill open positions. Meanwhile clinical trial activation is key, and our resources are dedicated to supporting our principal investigators through this process. We are pleased to report that our Regulatory Assistants have recently had their positions updated to better reflect the important work that they do as Regulatory Coordinators.

In addition, the CTO team is busy working on closing trials that are no longer accruing so that we can focus our efforts going forward on activating new and innovative protocols to serve our community. We are incredibly grateful for the work of both our regulatory and clinical teams in this area. Our activation pipeline has recently made great strides forward and we will soon be adding additional resources to streamline and improve our processes. We are excited to share that since March 1, we have closed 9 trials and activated 29 studies, with 4 activations in the last week!

I hope you will reach out if you have any suggestions, questions, or concerns. At the same time, please support our staff and one another. Everyone is working diligently to ensure 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

YaleNewHavenHealth Smilow Cancer Hospital | Yale CANCER CENTER
A Comprehensive Cancer Center Designated by the National Cancer Institute

CLINICAL TRIALS
KNOWLEDGE • RESEARCH • ADVANCES

May DART Accrual

Brain Tumor - 5

Breast Cancer - 1

Cellular Therapies - 3

Endocrine Cancers - 0

Gastrointestinal Cancers - 2

Clinical Trial Highlight

HIC 2000029001
PI: Patricia LoRusso, DO

A First-In-Human, Phase 1/2 Study Of CFI-402411, a Hematopoietic Progenitor Kinase-1 (HPK1) Inhibitor, as a Single Agent and in Combination With Pembrolizumab in Subjects With Advanced Solid Malignancies

This study is a first-in-human study evaluating the safety and tolerability of CFI-402411 in subjects with advanced solid malignancies, when CFI-402411 is administered as a single agent or in combination with pembrolizumab. CFI-402411 is an oral pill that blocks the function

Gynecologic Oncology - 3

Head & Neck Cancers - 4

Leukemia - 5

Lymphoma - 1

Melanoma - 2

Myeloma - 0

Pediatric Hematology/Oncology - 3

Prostate and Urologic Cancers - 1

Phase I - 12

Sarcoma - 0

Therapeutic Radiology - 2

Thoracic Oncology - 2

TOTAL = 46

of HPK1. Blocking HPK1 could stimulate an immune response against the tumor in patients. This immune response could be further enhanced when combined with pembrolizumab. The data obtained from this study will determine the dose and schedule and subject selection for further clinical studies.

Pre-clinical findings support further development of CFI-402411 as a novel anti-cancer agent, and the combination of CFI-402411 with pembrolizumab as a potential strategy to improve outcomes of subjects with advanced malignancies.
Learn More

Welcome Our New Staff!

Majed Albache, Clinical Research Coordinator

Joel Gonzalez, CRSL Research Assistant 1

Jane Kircaldie, Research Assistant, Regulatory Affairs

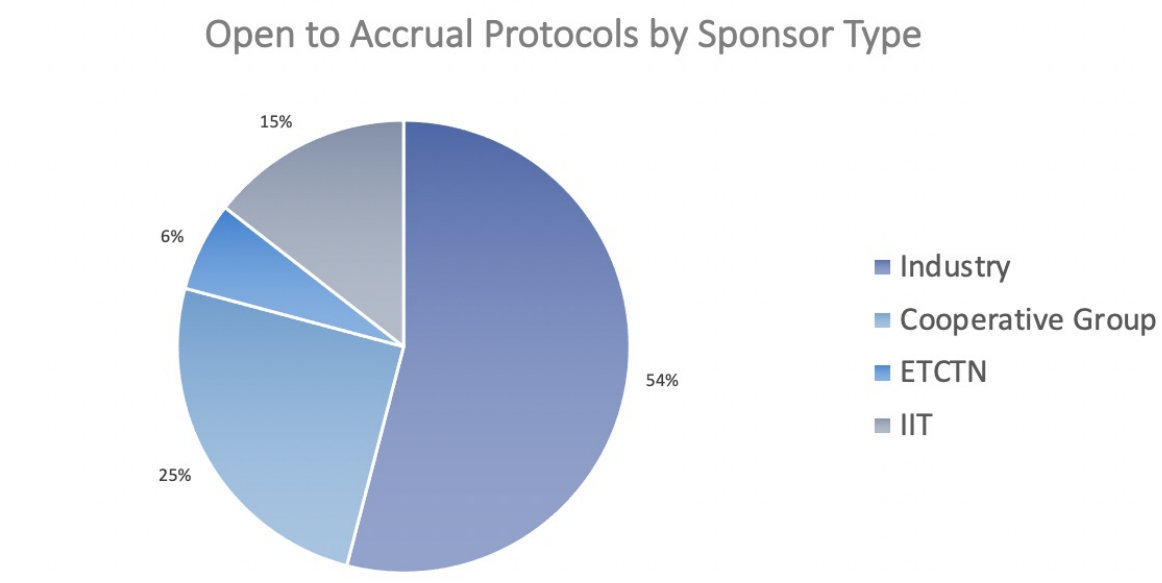
Anna Kraft, Project Manager

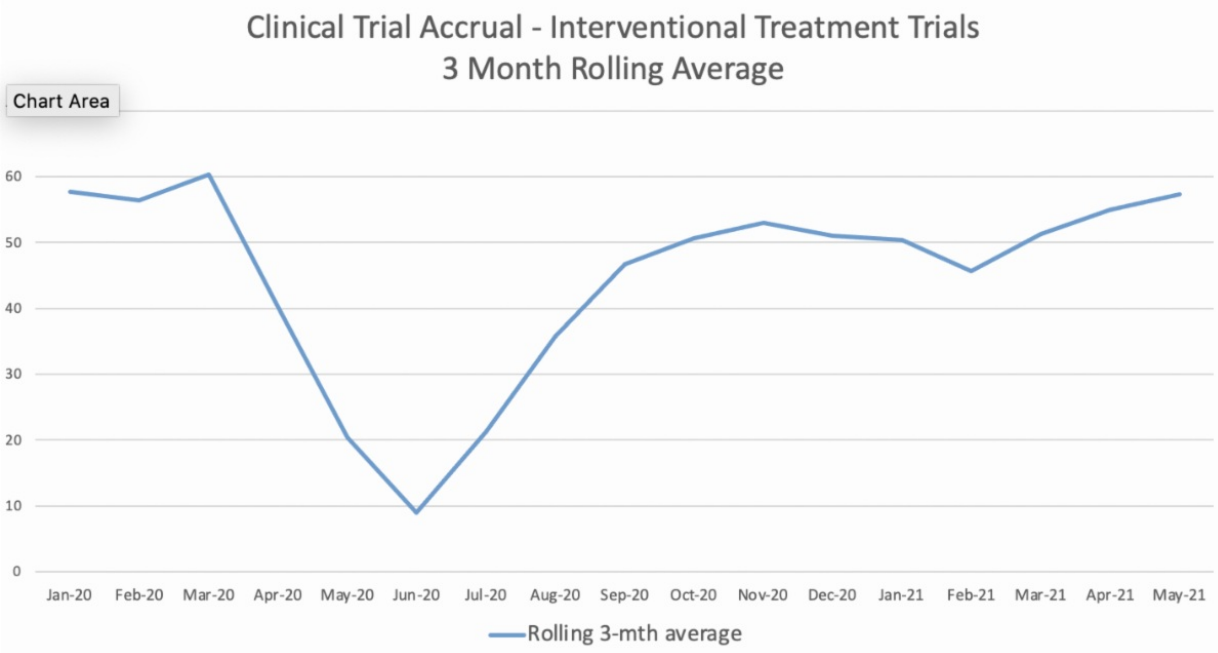
Paula Meyerholz, Clinical Research Coordinator

Madalena Pattacini, Regulatory Coordinator

Marissa Pierpont, Project Manager

Patrick Williams, Clinical Research Assistant





Staff Spotlight

Heather Gerrish, RN, pictured with Michele Messina, has been a passionate and dedicated Clinical Research Nurse in the Thoracic Oncology team for nearly 7 years. Heather also works weekends in the hospital and has a keen eye for reading a protocol and matching it to our hospital and CTO practices to identify potential issues before they arise. Like many nurses, Heather is also always concerned about our patients' experience and is always looking for ways to streamline and minimize the research impact on our patients and improve their care overall.

Heather consistently goes above and beyond to volunteer to fill a gap or to find a new way to share her knowledge and skills to strengthen the CTO. Most recently,

Staff Spotlight

Christine Ly joined the Clinical Trials Office as a regulatory assistant in 2016 and was quickly promoted to a Manager in 2019 to oversee the Lung and Phase I teams. Christine is a bright light on the regulatory team. She is a dedicated manager to her staff and a cheerleader for her team and the entire CTO. No one leaves a meeting with Christine without feeling just a little bit happier than they did before they met with her.

Christine does everything with a positive attitude. She keeps an even keel, even in rocky waters, and can calmly talk and problem-solve logically through any issue. She's also a devoted foodie, so no Monday meeting can start without a brief re-cap of her interesting weekend meals!

Heather has been assisting with coverage on the GU team while other members are out on leave temporarily filling a critical gap on short notice while continuing to support a robust Lung Team schedule. In addition to balancing her work demands, Heather also juggles a busy family schedule with two young boys who are very active in multiple sports teams. The Lung Team and the CTO appreciate the dedication that Heather brings to work on a daily basis.

Recently Opened Trials for Accrual

Phase II Study of Front Line Therapy With Nivolumab and Salvage Nivolumab + Ipilimumab in Patients With Advanced Renal Cell Carcinoma
HIC# 2000022534
Principal Investigator: Michael Hurwitz, MD, PhD

Comparing an Operation to Monitoring, With or Without Endocrine Therapy (COMET) Trial For Low Risk DCIS: A Phase III Prospective Randomized Trial
HIC# 2000025675
Principal Investigator: Mehra Golshan, MD, MBA

A Phase 2, Randomized, Open-label Three-arm Clinical Study to Evaluate the Safety and Efficacy of Lenvatinib (E7080/MK-7902) in Combination With Pembrolizumab (MK-3475) Versus Standard of Care Chemotherapy and Lenvatinib Monotherapy in Participants With Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma (R/M HNSCC) That Have Progressed After Platinum Therapy and Immunotherapy (PD-1/PD-L1 Inhibitors) (LEAP-009)
HIC# 2000029521
Principal Investigator: Barbara Burtness, MD

A Phase 3 Randomized Trial for Patients With De Novo AML Comparing Standard Therapy Including Gemtuzumab Ozogamicin (GO) to CPX-351 With GO, and the Addition of the FLT3 Inhibitor Gilteritinib for Patients With FLT3 Mutations
HIC# 2000028880
Principal Investigator: Nina Kadan-Lottick, MD

A Phase 1, Multi-center, Open Label First-in-Human Study With ABBV-CLS-579 Alone and in Combination With Anti-PD-1 in Subjects With Locally Advanced or Metastatic Tumors
HIC# 2000029783
Principal Investigator: Patricia LoRusso, DO

A Randomized, Double-blind, Placebo-controlled Phase III Multi-center Study of Azacitidine With or Without MBG453 for the Treatment of Patients With Intermediate, High or Very High Risk Myelodysplastic Syndrome (MDS) as Per IPSS-R, or Chronic Myelomonocytic Leukemia-2 (CMML-2)
HIC# 2000029580
Principal Investigator: Amer Zeidan, MBBS

A Multicenter, Non-randomized, Open-label Phase 1b Study to Determine the Maximum Tolerated and Recommended Phase 2 Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors
HIC# 2000028686
Principal Investigator: Patricia LoRusso, DO

A Phase 1, Open-label, Dose Finding Study of CC-90009 in Subjects With Relapsed, Refractory Acute Myeloid Leukemia
HIC# 2000020835
Principal Investigator: Amer Zeidan, MBBS

A First-In-Human, Phase 1/2 Study Of CFI-402411, a Hematopoietic Progenitor Kinase-1 (HPK1) Inhibitor, as a Single Agent and in Combination With Pembrolizumab in Subjects With Advanced Solid Malignancies
HIC# 2000029001
Principal Investigator: Patricia LoRusso, DO

A Phase 1a/1b Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of PY159 as a Single Agent and In Combination With Pembrolizumab in Subjects With Advanced Solid Tumors

HIC# 2000029378
Principal Investigator: Patricia LoRusso, DO
