July 2021

Newsletter

Clinical Research Advances

YaleNewHavenHealth Smilow Cancer Hospital | Yale CANCER CENTER

Dear Colleagues,

Our Clinical Trials Office team is working together and making very steady progress to ensure our clinical research operations are stronger, more responsive, and reflective of the clinical trial program our Cancer Center aspires to have. Our priority is to bring scientific advances from Yale Cancer Center laboratories and partnerships with industry directly to our patients. The outcomes of our clinical trials advance the field of oncology. We also must be sure we are reaching all patients, in all of our communities, to ensure access to clinical trials and cancer care.

Over the last month, 47 patients have started treatment on clinical trials and we have opened 5 new trials offering cutting edge therapies and closed 6 trials through our IRB. I am proud to announce the promotion of Sara Raboin to Senior Assistant Director for Clinical Trial Operations. Sara's leadership over the last several months has been instrumental for our team, and in achieving our overall goals in accruals, trial activation, and regulatory needs. I look forward to continuing to work closely with Sara and the entire team of Assistant Directors in the CTO to solidify our goals for the coming months.

Please reach out to me directly with suggestions, questions, or concerns at any time. I am grateful for everyone's support of our staff, and appreciate your 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 Research

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

CLINICAL TRIALS
KNOWLEDGE • RESEARCH • ADVANCES

June DART Accrual

Brain Tumor - 4

Breast Cancer - 2

Cellular Therapies - 1

Endocrine Cancers - 0

Gastrointestinal Cancers - 6

Gynecologic Oncology - 3

Head & Neck Cancers - 2

Our Phase I DART continues to pull together and make incredible progress for our patients. The team of nurses, advanced practice providers, clinical research coordinators, clinical research assistants, and regulatory staff work together to help each patient find the best treatment option for them, and through each step of their treatment plan on clinical trial. We are grateful to the entire Phase I team, and each

Leukemia - 2

Lymphoma - 1

Melanoma - 6

Myeloma - 1

Pediatric Hematology/Oncology - 1

Prostate and Urologic Cancers - 0

Phase I - 8

Sarcoma - 1

Therapeutic Radiology - 2

Thoracic Oncology - 7

TOTAL = 47

Welcome & Congratulations!

New Staff, Re-Hires, Promotions, and Transfers

Rachael Benane, CRSL Laboratory Coordinator

Kwasi Detwa Boateng, Manager, Clinical Trial Disease Team

Nicholas Brian Daniels, Clinical Research Nurse

Gabriella Douglas, Clinical Research Coordinator

Noah Friedland, Clinical Research Assistant 2

Ruth Gerth, Laboratory Manager, Saint Francis

Jamal Hanley, Clinical Research Assistant 2

Roliya Jackson, Clinical Research Assistant 2

Jan Kocur, Clinical Research Assistant 2

Alfredo Maldonado, Clinical Research Assistant 1

Ajoke Ogunleye, Regulatory Assistant

Aayushiben Anand Patel, Research Assistant 1

Sara Raboin, Senior Assistant Director, Clinical Trial Operations

Amy Rodrigues, Clinical Trials Team Manager

Fior Rodriguez, CRSL Laboratory Coordinator

of our Principal Investigators for their dedicated work.

Clinical Trial Highlights

HIC 2000029875
PI: Michael Cecchini, MD

A Phase 1/2a, Multi-Center, Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Preliminary Evidence of Antitumor Activity of JAB-3312 in Combination With Pembrolizumab or Binimetinib in Adult Patients With Advanced Solid Tumors

This study is a phase I study to assess the safety and tolerability and determine the recommended phase 2 dose (RP2D) of JAB-3312 in combination with PD1 inhibitor or MEK inhibitor in patients with advanced solid tumors.
Learn More

HIC 2000027242
PI: Jeremy Kortmansky, MD

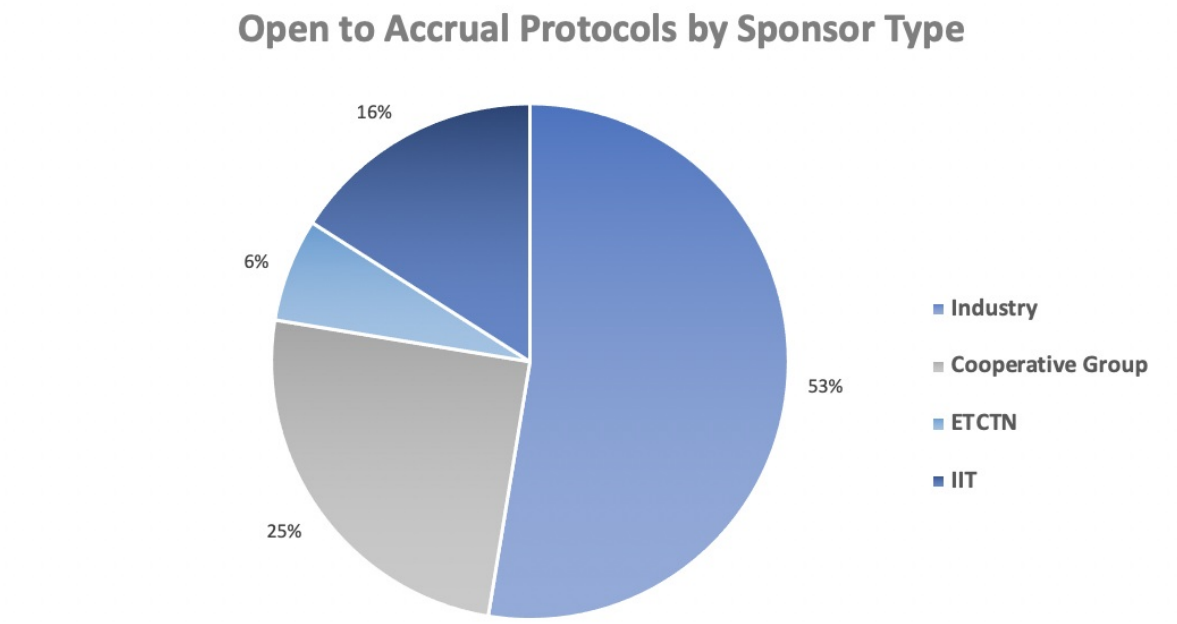
Phase II/III Study of Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients With Stage IIA Colon Cancer (COBRA)

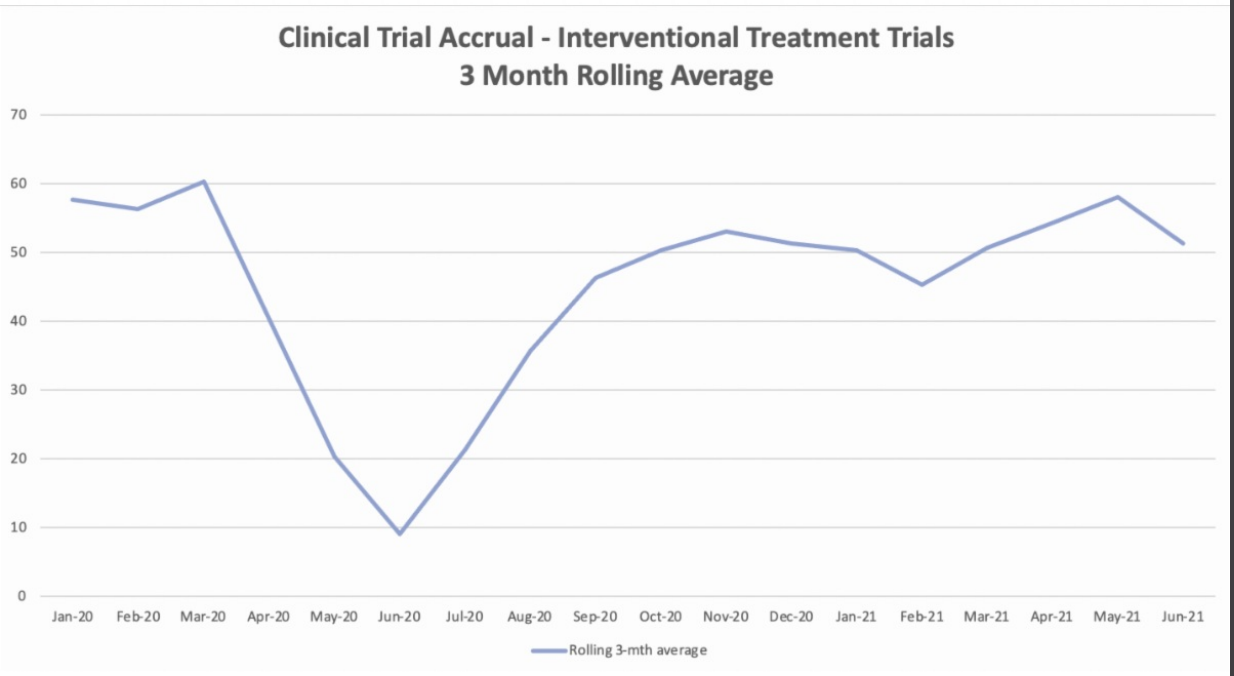
This phase II/III trial studies how well circulating tumor deoxyribonucleic acid (ctDNA) testing in the blood works in predicting treatment for patients with stage IIA colon cancer after surgery. ctDNA are circulating tumor cells that are shed by tumors into the blood. Finding ctDNA in the blood means that there is very likely some small amounts of cancer that remain after surgery. However, this cancer, if detected, cannot be found on other tests usually used to find cancer, as it is too small. Testing for ctDNA levels may help identify patients with colon cancer after surgery who do benefit, and those who do not benefit, from receiving chemotherapy.
Learn More

Floriel Selenica, Clinical Research Assistant 2

Rupinder Singh, Clinical Research Coordinator

Toni Tew, Senior Project Manager, Training and Education





Staff Spotlight: Mandy Izokaitis

Staff Spotlight: Marissa Pierpont

Mandy Izokaitis, pictured here with her daughter Kaylee, joined the Clinical Trials Office as a Clinical Research Assistant in our Waterbury Care Center in 2015. The Smilow Cancer Hospital Care Center in Waterbury was one of the first Care Centers to integrate with Smilow and Yale Cancer Center in 2012, and Mandy had joined their practice in 2010. Mandy consistently goes above and beyond for our patients on clinical trials and her dedication and perseverance have directly made navigating a clinical trial a smoother process for them.

Mandy is a true team player, not just in her Center but for the entire Care Center team. She regularly provides coverage for others and is always willing to lend a helping hand to her teammates. Mandy is an amazing problem solver and is great at finding solutions when faced with a roadblock. Something you may not know about Mandy is that she is a Reiki Master. The Care Centers and the CTO are lucky to have her on our team!

Marissa Pierpont has worked at in our Clinical Research Support Lab (CRSL) since 2017. Currently, Marissa is one of our CRSL Project Managers. In this role, she coordinates the research collections for multiple oncology disease teams. She acts as a resource to site Principal Investigators and Clinical Trials Team Managers to ensure samples are collected and processed per protocol requirements to meet the needs of each study. Our Clinical Trials Office has recently seen an increase in both the volume and complexity of oncology research protocols and when protocols are opened that require novel or complicated coordination, Marissa goes above and beyond to ensure every detail is planned and communicated. She has helped to coordinate with both internal and external labs, coordinates sample collection needs across the states of Connecticut and Rhode Island, creates research collection builds for research subjects, attends regular meetings with study team members, and always offers to help her colleagues when needed. Thank you for your leadership and dedication, Marissa!

Recently Opened Trials for Accrual

A Phase 1/2a, Multi-Center, Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Preliminary Evidence of Antitumor Activity of JAB-3312 in Combination With Pembrolizumab or Binimetinib in Adult Patients With Advanced Solid Tumors
HIC# 2000029875
Principal Investigator: Michael Cecchini, MD

Prostate Cancer Outcomes: An International Registry to Improve Outcomes in Men With Advanced Prostate Cancer (IRONMAN)
HIC# 2000023726
Principal Investigator: Daniel Petrylak, MD, PhD

A Phase 3, Randomized, Double-Blind Study of Pembrolizumab Versus Placebo in Combination With Adjuvant Chemotherapy With or Without Radiotherapy for the Treatment of Newly Diagnosed High-Risk Endometrial Cancer After Surgery With Curative Intent (KEYNOTE-B21 / ENGOT-en11 / GOG-3053)
HIC# 2000029578
Principal Investigator: Alessandro Santin, MD

A Prospective, Multi-Center Investigational Study of IMMray PanCan-d Diagnostic Platform for Early

Detection of Pancreatic Ductal Adenocarcinoma in High-Risk Populations (PANFAM-1)
HIC# 2000022735
Principal Investigator: James Farrell, MD

Comparing the Clinical Impact of Pancreatic Cyst Surveillance Programs
HIC# 2000027478
Principal Investigator: James Farrell, MD

Phase II/III Study of Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients With Stage IIA Colon Cancer (COBRA)
HIC# 2000027242
Principal Investigator: Jeremy Kortmansky, MD
