September 2021

Newsletter

Clinical Research Advances

YaleNewHavenHealth Smilow Cancer Hospital | Yale CANCER CENTER

Dear Colleagues,

I am proud to announce that we rallied to enroll 67 patients on clinical trials during the month of August! Thank you to every member of our Clinical Trials Office Staff, our CRSL team, and our physicians and nurses for prioritizing clinical research. I realize that we continue to have obstacles to overcome, but am proud of the progress that's been made over the last several months. We will continue to look for ways to increase the support for our current staff and recruit highly qualified new staff, and as that happens I am confident that our accruals will continue to be strong as a result.

There have been 52 trials activated since March 1, 2021. While this is still short of our goal of approximately 14 trials per month, our immediate priority remains to be staffing and stabilization of the CTO to ensure on-going patient safety and regulatory compliance. We are continuing to hire as well as add resources to augment the CTO, in regulatory, CRSL, as well as on the clinical team. Once we are confident in the office stabilization, our efforts to further prioritize and support an increased rate of trial activation will follow.

Please reach out to me, or Alyssa Gateman, Interim Administrative Director of the Clinical Trials Office, directly with questions or concerns. Thank you for your continued support of our staff and 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

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CLINICAL TRIALS
KNOWLEDGE • RESEARCH • ADVANCES

August DART Accrual

Brain Tumor - 4

Breast Cancer - 9

Cellular Therapies - 2

Endocrine Cancers - 0

SWOG Diversity, Equity & Inclusion Research Champions

SWOG is introducing DEI Champions to collaborate with research committees and study teams to provide evidence-based guidance for increasing diverse representation in SWOG research. DEI Champions will work with research committees and study teams to identify action plans to increase diversity and equity in

Gastrointestinal Cancers - 5

Gynecologic Oncology - 7

Head & Neck Cancers - 6

Leukemia - 5

Lymphoma - 2

Melanoma - 3

Myeloma - 1

Pediatric Hematology/Oncology - 2

Prostate and Urologic Cancers - 0

Phase I - 13

Sarcoma - 0

Therapeutic Radiology - 4

Thoracic Oncology - 4

TOTAL = 67

Welcome New Staff!

Monica Gomes
Clinical Research Assistant
GU Team

Michaela Wright
Clinical Research Assistant
Phase I Team

Rachel Brodeur
Clinical Research Coordinator
Breast Team

Manushi Gandhi
Clinical Research Assistant
Lymphoma Team

Daniel Moncayo
Clinical Research Coordinator
Leukemia Team

Jamie Goodner-Bingham
Research Assistant
CRSL Team

Devon Riley
Research Assistant
Regulatory Team

Phyllis Nortey
Clinical Research Assistant
Neuro Team

Deborah Mitchell
Clinical Research Nurse

research participation.

The deadline to apply for consideration as a SWOG DEI Champion is September 24.
Learn More

Clinical Trial Highlights

HIC 2000027406
PI: Scott Huntington, MD, MPH, MSc

A Phase 1/2 Study of Oral LOXO-305 in Patients With Previously Treated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) or Non-Hodgkin Lymphoma (NHL)

This study includes 3 parts: phase 1 (LOXO-305 monotherapy dose escalation and dose expansion), phase 1b (LOXO-305 combination therapy dose expansion), and phase 2 (LOXO-305 monotherapy dose expansion). In phase 1, patients will be enrolled using an accelerated titration design. The starting dose of LOXO-305 in oral tablet form is 25 mg/day (e.g., 25 mg once daily [QD]). Once the MTD and/or RP2D is identified in phase 1 dose escalation, enrollment will continue to phase 1 dose expansion and can commence to phase 1b (Arms A and B). For phase 2, patients will be enrolled to one of seven phase 2 dose expansion cohorts depending on tumor histology and prior treatment history. Cycle length will be 28 days.
Learn More

HIC 2000030853
PI: Michael Cecchini, MD

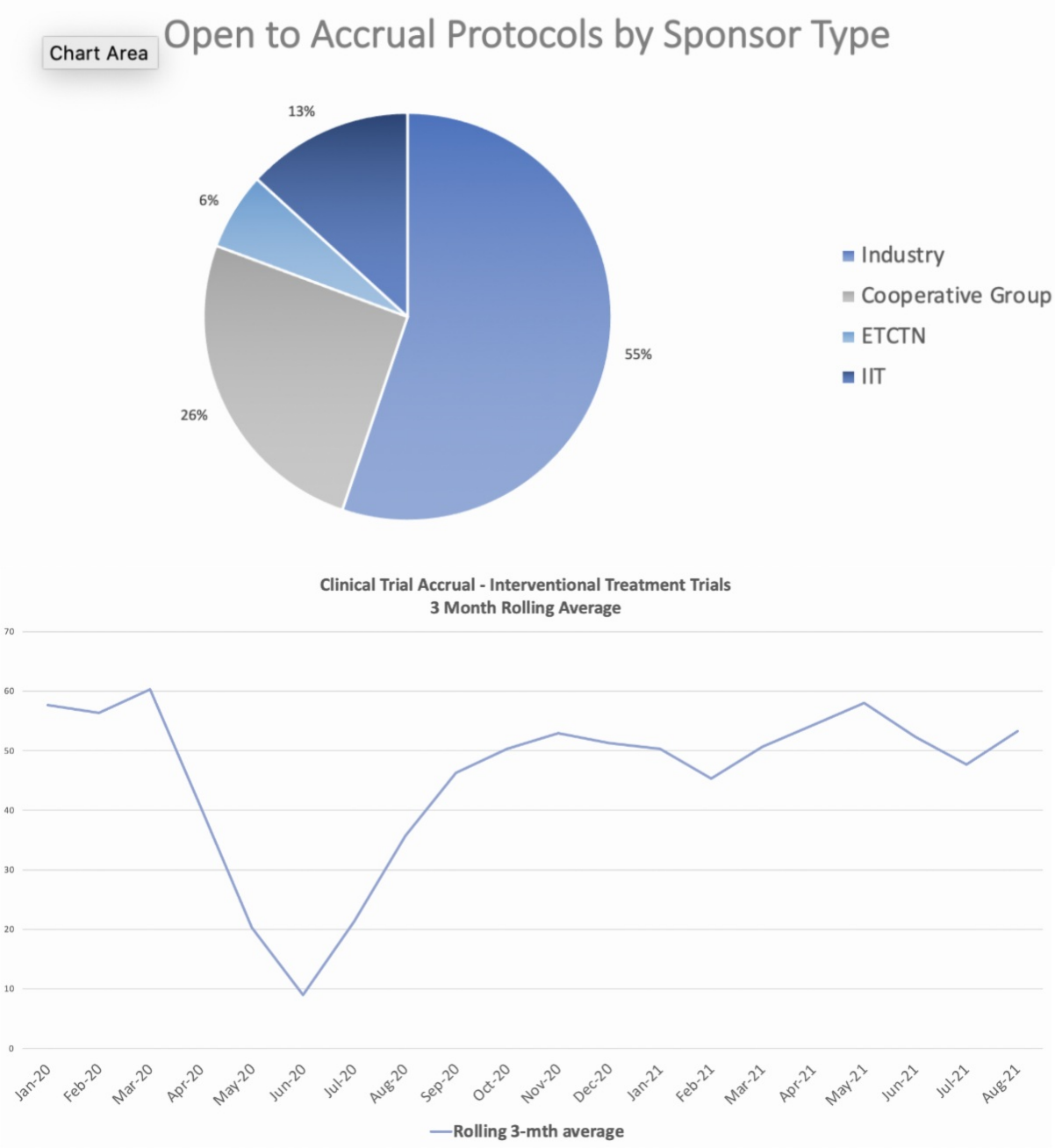
BAY1895344 Plus Topoisomerase-1 (Top1) Inhibitors in Patients With Advanced Solid Tumors, Phase I Studies With Expansion Cohorts in Small Cell Lung Carcinoma (SCLC), Poorly Differentiated Neuroendocrine Carcinoma (PD-NEC) and Pancreatic Adenocarcinoma (PDA)

This phase I trial investigates the side effects and best dose of BAY 1895344 when given together with usual chemotherapy (irinotecan liposome or topotecan) in treating patients with solid tumors that have spread to other places in the body (advanced), with a specific focus on small cell lung cancer, poorly differentiated neuroendocrine cancer, and pancreatic cancer. BAY 1895344 may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. Chemotherapy drugs, such as irinotecan liposome and topotecan, 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. Adding BAY 1895344 to irinotecan liposome or topotecan may help to slow the growth of tumors for longer than

Leukemia Team

Jessica McKenzie
Clinical Trials Team Manager
GU/ENDO/SARC

seen with those drugs alone.
Learn More

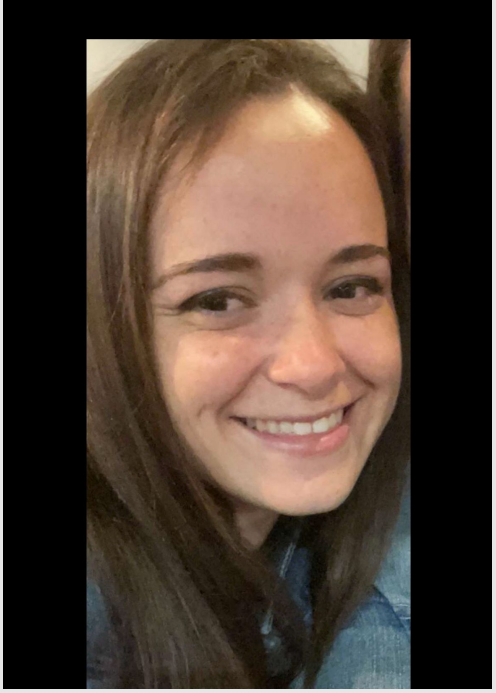


Staff Spotlight: Norma Gavillan

Staff Spotlight: Samantha Varney

Norma Gavillan has been an Administrative Assistant in the Clinical Trials Office for eighteen months; she had just started with our department when the COVID-19 health and work restrictions went into effect. She's one of our first employees that was trained and onboarded remotely and not only did she rise to the challenge but she excelled and showed us all how it could be done! As essential staff returned back to campus, Norma shifted gears quickly and was instrumental in helping staff return by coordinating the cleaning of workspaces with EHS and preparing PPE kits to ensure everyone's safe return.

Norma's primary role consists of managing the therapeutic radiology research department's daily needs, including onboarding and off boarding new staff, scheduling meetings, assisting in audit prep, ordering office equipment and supplies, archiving study documents, as well as working closely with HR, Assistant Directors and Managers to schedule interviews for vacant positions with appropriate department staff. Norma is a real self-starter and comes to work every day with a smile and a "how can I help" attitude. She and our two other administrative assistants in the CTO keep a department of 160 organized so that we are ready to take on each day's challenges. We are so thankful that they are very good at what they do!



Samantha Varney has been a part of our Regulatory Office since July of 2018. She first joined the office as a Research Assistant and was promoted to Regulatory Coordinator in March 2019. Sam has served on multiple Disease Aligned Research Teams (DARTs) throughout the years and now spends her time supporting the GI DART.

Sam is an incredible asset to our Regulatory office. She is always looking to help others and jumps in to assist wherever she is needed! She is wonderfully friendly to everyone and brings an old soul vibe to everything that she does. Back in the office, she was an amazing plant mom to the office greens and her desk served as a mini greenhouse. Sam is our favorite regulatory vegan, except when it comes to good cheese! She was known to bring in delicious vegan treats, including chocolate hummus with fresh fruit or bagels and vegan cream cheese! Sam is always excited to meet new folks, so be sure to say hi when you see her pop into your next Zoom meeting!

Recently Opened Trials for Accrual

A Randomized Phase II Trial Of Circulating Tumor DNA-Guided Second Line Adjuvant Therapy For High Residual Risk, Stage II-III, Hormone Receptor Positive, HER2 Negative Breast Cancer
HIC# 2000029678

Principal Investigator: Lajos Pusztai, MD, DPhil

An Open-label Study of ALPN-202 in Subjects With Advanced Malignancies (NEON-1)
HIC# 2000029136
Principal Investigator: Mario Sznol, MD

A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Enzastaurin Added to Temozolomide During and Following Radiation Therapy in Newly Diagnosed Glioblastoma Patients Who Possess the Novel Genomic Biomarker DGM1
HIC# 2000029377
Principal Investigator: Antonio Omuro, MD

A Phase 1/2 Study of Oral LOXO-305 in Patients With Previously Treated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) or Non-Hodgkin Lymphoma (NHL)
HIC# 2000027406
Principal Investigator: Scott Huntington, MD, MPH, MSc

Phase I, First-in-human, Open-label, Dose Escalation Trial to Evaluate Safety, Pharmacokinetics, Pharmacodynamics, and Anti-tumor Activity of BNT152+153 in Patients With Solid Tumors
HIC# 2000030206
Principal Investigator: Patricia LoRusso, DO

A Phase I/II Trial of Reduced Intensity Conditioning and Familial HLA-Mismatched Bone Marrow Transplantation in Children With Non-Malignant Disorders
HIC# 2000025196
Principal Investigator: Niketa Shah, MD

A Phase 2 Open Label Study of Sacituzumab Govitecan (IMMU-132) in Subjects With Metastatic Solid Tumors
HIC# 2000025243
Principal Investigator: Alessandro Santin, MD

Phase 2/3 Trial to Evaluate Margetuximab in Combination With INCMGA00012 and Chemotherapy or MGD013 and Chemotherapy in Patients With Metastatic or Locally Advanced, Treatment-naïve, HER2-Positive Gastric or Gastroesophageal Junction Cancer
HIC# 2000026325
Principal Investigator: Jill Lacy, MD

Phase 1B Study of PTC299 in Relapsed/Refractory Acute Leukemias
HIC# 2000024928
Principal Investigator: Amer Zeidan, MBBS
