

October 2021

Newsletter

Clinical Research Advances

YaleNewHavenHealth
Smilow Cancer Hospital

Yale
CANCER
CENTER

Dear Colleagues,

Over the last month we have seen significant progress in the growth of our leadership team, and in our planning progress. I am so pleased to have Amber Selvidge, Senior Assistant Director of the Clinical Trials Office and Director of Regulatory Affairs, and Diane Wall, Regional Assistant Director of the Care Centers, on our team. In addition, Adam Roshka, has been promoted to Director of Finance and Administration for both the CTO and YCCI in recognition of his strong management and leadership in clinical research.

I look forward to working closely with Dr. Stacey Stein as Assistant Medical Director of the Clinical Trials Office and Dr. Neal Fischbach, Assistant Medical Director of the Clinical Trials Office for the Care Center Network. Please join us in welcoming Dr. Stein and Dr. Fischbach to their new positions. We are confident that the addition of two new Assistant Medical Directors will help provide continuity and leadership at all our clinical locations.

As part of our work to improve processes in the CTO, new SOPs have been developed for Principal Investigators. PIs have significant roles and responsibilities in the new SOPs and therefore a series of mandatory training sessions have been scheduled. **It is imperative that all PIs attend one of the following training sessions next week (Zoom links embedded):**

- [TODAY, Monday, October 11 from 6:30-7:30pm](#)
- [Wednesday, October 13 from 7:30-8:30am](#)
- [Thursday, October 14 from 9:30-10:30am](#)

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
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A Comprehensive Cancer Center Designated
by the National Cancer Institute

Staff Spotlight:
Lindsey Waggoner

Survivor Spotlight:
Jack White



Lindsey Waggoner has worked in research for nearly three years and over half that time has been with the Yale Cancer Center Clinical Trials Office at our Greenwich location. In her role as a Clinical Research Nurse, Lindsey is responsible for assisting with patient care for patients enrolled on clinical trials. She participates in the informed consent process, helps to clear patients for treatment based on protocol criteria, and acts as a resource during a very challenging time in our patients' lives.

Over the last several months, Lindsey has also assisted with coverage on the GU team in New Haven by filling a critical gap on short notice while continuing to support enrollment and patient volume at our Greenwich location. Lindsey values putting patients' needs at the forefront of what she does and is grateful to be part of the process in bringing specialized care to our patients. Thank you Lindsey, for all that you do to support our mission and our patients!



Each time Jack White starts a new entry in the notebook he uses for work and personal reminders, he writes a series of numbers in the corner of the page. The left number never changes: It's always six. It stands for the six sessions of immunotherapy he had on a clinical trial at Smilow Cancer Hospital to treat his non-small cell lung cancer. The right number changes every day. It marks the amount of time that has passed since his final immunotherapy session. On August 31, 2021, he wrote "8," to celebrate a remarkable eight years of his cancer being in remission. "It's a reminder of how far out I am from treatment and how far I've come," he says.

In the eight years since his treatment, Mr. White has remained cancer free. He and his wife, Susan, have celebrated many family milestones, including the birth of four grandchildren. He is set to retire this month. He plans to take guitar lessons from his son-in-law Rick. He relishes watching the birds, foxes and other wildlife that inhabit his 13-acre property, in the company of his Chihuahua, Jimmy, who joined the family around the time that Mr. White finished his last treatment. "Getting Jimmy was a way of me saying, 'I am not going anywhere,' and I didn't," he said.

[Read Jack's story](#)

Welcome New Staff!

September Accrual

Brain Tumor - 5

Breast Cancer - 14

Cellular Therapies - 2

Endocrine Cancers - 0

Gastrointestinal Cancers - 4

Gynecologic Oncology - 6

Head & Neck Cancers - 1

Leukemia - 2

Lymphoma - 3

Melanoma - 1

Myeloma - 2

Pediatric Hematology/Oncology - 0

Prostate and Urologic Cancers - 1

Phase I - 5

Sarcoma - 0

Therapeutic Radiology - 2

Thoracic Oncology - 5

TOTAL = 53

Master CTAs

A Master CTA is a separate contract between Yale and a Sponsor that does not reference a specific study. Instead, each future study is facilitated using a simpler contract, with study-specific information.

- Typically controls all the terms of the contract; however, certain Master CTAs require additional negotiation of payment terms
- Not available for IITs or for studies through other institutions or mechanisms
- Most Master CTAs are valid for a specified term, but some do not have a term. Changes in

Amber Selvidge, Senior Assistant
Director of Regulatory Affairs

Diane Wall, Regional Assistant
Director of the Care Centers

Roslyn Yi, CRSL Project Manager

Mark Barrow, Clinical Research
Assistant; Waterford/Westerly Cancer
Centers

Kelly Provenzano, Clinical Research
Assistant; Lung Team

Martha J (MJ) Williams, Clinical
Research Assistant; (Heme) Cell
Therapy Team

Marissa Hasbargen, Clinical
Research Assistant; GI Team

Reynaldo Trinidad, Clinical
Research Assistant; GU Team

Hsien-Ning Liu, Regulatory
Coordinator

Justin Stevens, Regulatory
Assistant

Alyssa Roberti, Clinical Research
Coordinator; H&N Team

Pallavi Kasturi, Clinical Research
Assistant; (Heme) Lymphoma Team

Kayla Jaikaran, Clinical Research
Assistant; Phase I Team

Zaadia Arzu, Clinical Research
Coordinator; Phase I Team

Rosalina Massie, Interim Regulatory
Manager 2

Stephanie Pirucki, Interim
Regulatory Coordinator

Cristina Panhans, Interim
Regulatory Coordinator

Amy Pflugrath, Interim Regulatory
Coordinator

Sharell Risher, Interim Regulatory
Coordinator

Gloria Dorsette, Interim Regulatory
Research Assistant

Ashley Beal, Interim Regulatory
Research Assistant

Ali Laske, Interim Regulatory
Research Assistant

staff at the sponsor-level and changes in guidance from the Office of General Counsel could lead to a Master CTA falling out of use after a long period of time.

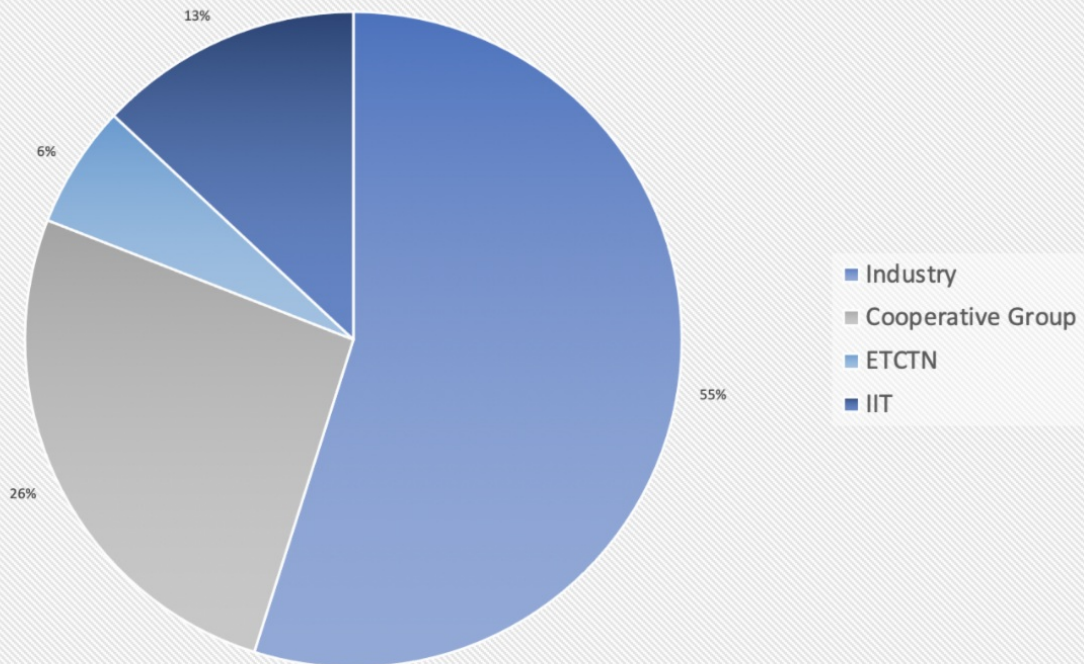
Sponsors and Contract Research Organizations (CROs) with whom Yale currently has a Master CTA:

1. Abbott Vascular Solutions
2. AbbVie
3. Alexion Pharmaceutical Inc.
4. Amgen
5. Astellas Pharma
6. AstraZeneca
7. Bayer Healthcare
8. Biogen
9. Biotronik
10. Boehringer Ingelheim
11. Bristol-Myers Squibb
12. Celgene
13. Clovis Oncology
14. EMD Serono
15. Genentech
16. Genzyme
17. Gilead Sciences
18. GlaxoSmithKline
19. Intercept Pharmaceuticals
20. InterMune
21. Janssen
22. Medtronic
23. Merck
24. Millennium Pharmaceuticals
25. Natera, Inc.
26. Novartis
27. Novo Nordisk
28. Pfizer
29. PPD (CRO)
30. Sanofi-USA
31. SeaGen
32. Target PharmaSolutions
33. UCB BioPharma SPRL
34. Vertex Pharmaceuticals, Inc.

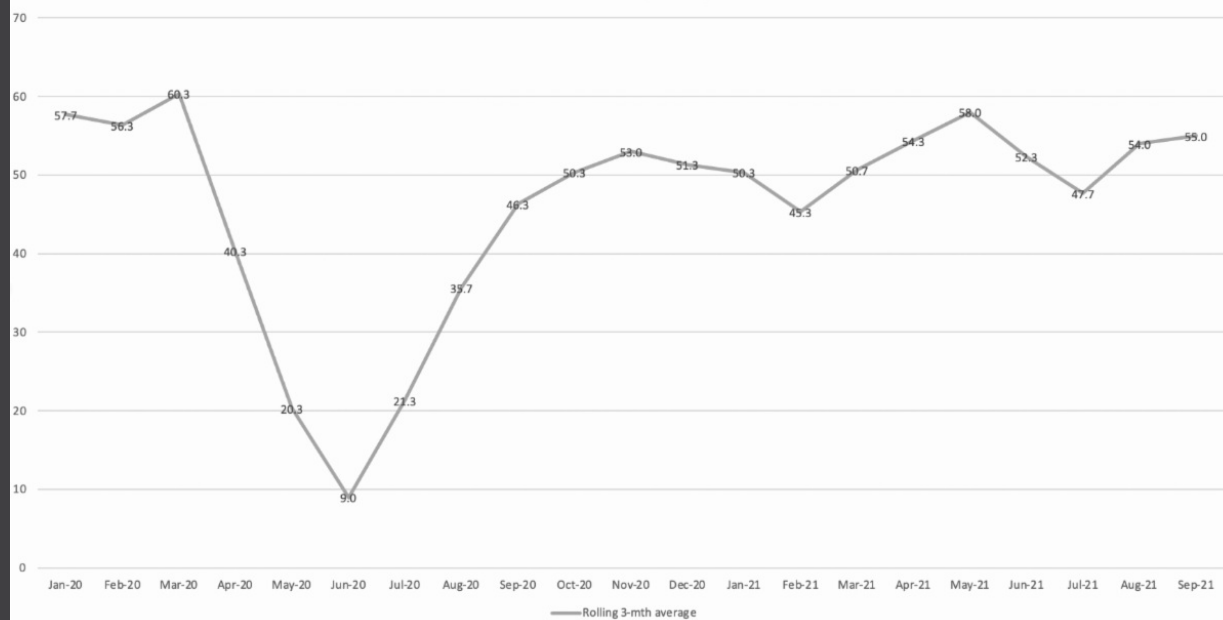
For more information, please contact:

Erica Rocco, BS, CCRP
Regulatory Project Manager

Open to Accrual Protocols by Sponsor Type



Clinical Trial Accrual - Interventional Treatment Trials
3 Month Rolling Average



Recently Opened Trials for Accrual

[A Phase 1b/2, Open-Label, Randomized Platform Study Evaluating The Efficacy and Safety of AB928 Based Treatment Combinations in Patients With Metastatic Colorectal Cancer](#)

HIC# 2000029908

Principal Investigator: Michael Cecchini, MD

[A Phase 4, Single-arm, Open-label Clinical Study of Pembrolizumab \(MK-3475\) to Evaluate the Efficacy and Safety of MK-3475 Plus Carboplatin and Paclitaxel as First-line Treatment of Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma](#)

HIC# 2000030195

Principal Investigator: Barbara Burtness, MD

Phase III Trial of Post-Surgical Single Fraction Stereotactic Radiosurgery (SRS) Compared With Fractionated SRS for Resected Metastatic Brain Disease

HIC# 2000026966

Principal Investigator: Yi An, MD

A Randomized Phase II Study of Trastuzumab and Pertuzumab (TP) Compared to Cetuximab and Irinotecan (CETIRI) in Advanced/Metastatic Colorectal Cancer (mCRC) With HER-2 Amplification

HIC# 2000022058

Principal Investigator: Jeremy Kortmansky, MD

A Randomized, Open-Label, Phase 1-2 Study of ASTX727 Low Dose (ASTX727 LD) Extended Schedule in Subjects With Lower Risk (IPSS Low or Intermediate-1) Myelodysplastic Syndromes (MDS)

HIC# 2000026348

Principal Investigator: Amer Zeidan, MBBS

Yale Cancer Center | Clinical Trials Office | (203) 785-5702 | www.yalecancercenter.org/trials

STAY CONNECTED

