

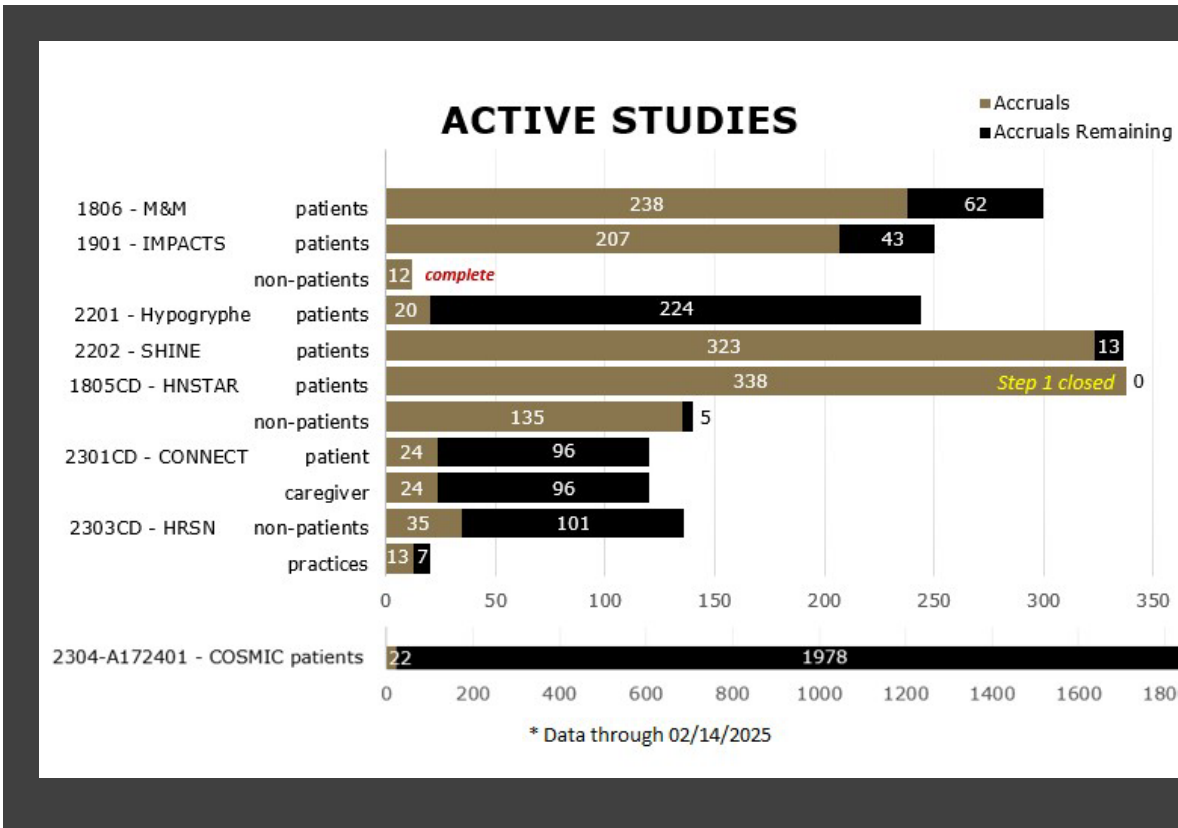


COMMUNITY CONNECTION

Quarterly Newsletter

February 2025

Study Accruals



Study Highlight: COSMIC

**Complementary Options for Symptom Management in Cancer (COSMIC):
Assessing Benefits and Harms of Cannabis and Cannabinoid Use Among a Cohort
of Cancer Patients Treated in Community Oncology Clinics**



Activated on January 15, 2025 and enrolling!

Study Design: This prospective cohort study will examine the association between cannabis and cannabinoid use and cancer-related symptoms for a period of one year in adults with newly diagnosed breast, colorectal, melanoma, non-Hodgkin lymphoma, or non-small cell lung cancer (NSCLC) who are planning or recently started to receive one or more systemic cancer directed therapies with chemotherapy and/or immune check point inhibitors (ICIs) targeting PD-1, PD-L1 or CTLA-4. In a subsample of non-small cell lung cancer patients, this study also examines potential drug interactions and impacts of cannabis and cannabinoid use on inflammatory and immune response

Study Schema:

Identification of Potentially Eligible Patients

(cancer type [breast, colorectal, melanoma, non-Hodgkin lymphoma, non-small cell lung treatment regimen [chemotherapy and/or ICI])

Obtain Informed Consent

Confidential Online Self-reported Screening Survey:

cannabis use, use of complementary therapies, and state of residence.

Strata

Cannabis and Cannabinoid Use:

- **Non-Current Users (did not use in the past 30 days)**
 - Never users
 - Non-recent users (used more than 30 days ago)
- **Current users (used in the past 30 days)**
 - Frequent Users (one or more times per week, every day or almost every day)
 - Infrequent Users (one or more times a month but less than weekly)

Cannabis Policy of State of Residence: (Medical only, Recreational/Medical, CBD only/no cannabis)

Enroll potential participant if they meet all eligibility after the screening survey is complete.

Baseline

Confidential Baseline Online Survey: cancer-related symptoms, cannabis and cannabinoid use (e.g., modes, cannabinoid type, concentration, frequency, perceptions of benefits and harms, adverse effects, reasons for use), substance use, demographics, health-related quality of life, social support, and use of other medications and complementary therapies.

Medical Record Data Forms: cancer and medical history, cancer treatment, select labs, comorbidities, concomitant medications, and participant 9-digit zip code for location analysis.

Months 1-12 (every 30 days)

Confidential Monthly Online Survey: cancer-related symptoms, cannabis and cannabinoid use (see above), use of other medications and complementary therapies.

***Months 6 & 12 additional items:** health-related quality of life, social support, cannabis use disorder (users only)

Medical Record Data Forms will be updated at least quarterly (i.e., Months 3, 6, 9 and 12).

Study Sample: N=2000 participants (500 participants per cannabis use stratum with a minimum of 100 and maximum of 200 participants per state cannabis policy stratum)

Study Duration: 12 months

Brief Eligibility: Adults with newly diagnosed cancer (i.e., breast, colorectal, melanoma, non-Hodgkin lymphoma, non-small cell lung) who are planning to receive one or more systemic cancer directed therapies with chemotherapy and/or ICIs targeting PD-1, PD-L1 or CTLA-4. If unable to engage patient before treatment starts, enrollment is allowed prior to the start of Cycle 2.

Document Access:

- The protocol documents are available on the [CTSU](#) website.
- The *Helpful Guide* is available on the [WAKENCORP](#) website.
- Required training is available: **Course Title in CLASS: WAKE: WF2304-A172401 COSMIC Introductory Site Training.**
- Recruitment Materials can be requested using this link: [Recruitment Materials REDCap Survey](#)

Sites interested in participating should contact NCORP@wakehealth.edu; Attn: WF2304-A172401 and request start-up information.

Top Accruing CC Affiliates*

Patient Accruals

| Rank | Affiliates | Accruals |
|------|---|----------|
| 1 | NC002 - Atrium Health Wake Forest Baptist Cancer Center | 7 |
| 2 | VA010 - VCU/Massey Cancer Center (VCU MU) | 4 |
| | SC015 - Self Regional Healthcare (MUSC MU) | |
| | IL042 - John H Stroger Jr Hospital of Cook County(Stroger MU) | |

* Data from 10/01/2024 - 12/31/2024

Non-Patient Accruals (excluding practice)

| Rank | Affiliates | Accruals |
|------|---|----------|
| 1 | SC058 - Tideland's Georgetown Memorial Hospital (MUSC MU) | 2 |

* Data from 10/01/2024 - 12/31/2024

Top Accruing CCDR Affiliates*

Patient Accruals

| Rank | Affiliates | Accruals |
|------|--|----------|
| 1 | WI212 - ThedaCare Regional Cancer Center (WINCORP) | 4 |
| 2 | MN014 - Park Nicollet Clinic - Saint Louis Park (MMCORC) | 3 |
| | SC024 - Spartanburg Medical Center (UPSTATE) | |
| | WI028 - Aspirus Regional Cancer Center (CROWN) | |

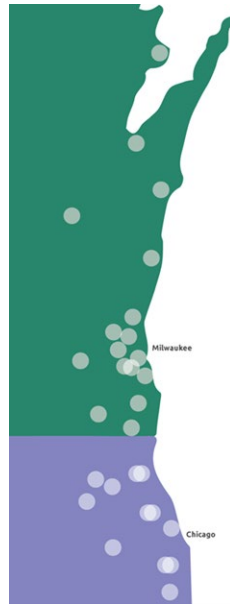
* Data from 10/01/2024 - 12/31/2024

Non-Patient Accruals (excluding practice)

| Rank | Affiliates | Accruals |
|------|--|----------|
| 1 | WI212 - ThedaCare Regional Cancer Center (WINCORP) | 6 |
| 2 | MN013- Hennepin County Medical Center (MMCORC) | 2 |

* Data from 10/01/2024 - 12/31/2024

Site Highlight: Aurora NCORP



The Aurora NCORP enrolls patients to a variety of NCI-sponsored treatment, cancer control and cancer care delivery research (CCDR) trials at more than 30 sites. Advocate Health is an integrated health system located in Midwest and Southeastern states. The Aurora NCORP covers the research sites located in the Midwest, specifically Wisconsin and Illinois.

The Aurora NCORP is led by Principal Investigators Drs. Thomas (Tom) Saphner and Sigrun (Siggy) Hallmeyer. Dr. Rebecca McFall serves as the principal investigator for pediatric oncology research.

At any given time, at least 50 NCI-sponsored trials are open at our NCORP. We are members of six of the seven research bases, including the Children's Oncology Group (COG). Nearly 350 team members make up the Aurora NCORP. This includes more than 200 physician investigators and advanced practice providers.

Aurora NCORP highlights include:

- NCORP is the **largest federal grant** at Advocate Health – Midwest Region.
-

- We are one of only a few NCORPs that serve both **adult and pediatric patients**.
- We exceeded our year 10 accrual goal; this was the second time in four years.
- In the first 10 years of the grant, we had more than **2,300 accruals, 1,200 special entry** enrollments and submitted roughly **1,800 biospecimens**.
- We received Platinum Awards in two categories at the Annual NCORP meeting hosted by the NCI in August 2024: **200 or more accruals** to cancer control and treatment trials and **top practice accruals** to Cancer Care Delivery Research (CCDR) trials. **Sixteen individual investigators** were also honored.

We enrolled 338 patients to the **NHLBI-MDS** trial, accounting for 16% of its total accrual. Three of our sites were among the top 15 enrolling sites; Aurora Cancer Care – Southern Lakes was the highest enrolling trial site, with 147 accruals

NCORP Principal Investigators (PI): Thomas Saphner, MD, and Sigrun Hallmeyer, MD

Pediatric Oncology PI: Rebecca McFall, MD

CCDR Lead: Thomas Saphner, MD

NCORP Administrator: Neha Glandt

Do you have site or staff that should be recognized? Please submit recommendations to NCORP@wakehealth.edu with "Quarterly Newsletter Site/Staff Highlight" in the subject line.

Top Accruing Investigators by Study

(from 10/01/2024 - 12/31/2024) Patient and Dyad Accruals

WF-1805CD

1. **Andrew Huang, MD (2) - WI028 (CROWN)**
2. **4 other investigators with 2 accrual**

WF-1806

1. **Thomas Lad, MD (4) - IL042 (Stroger MU)**
2. **9 other investigators with 1 accrual**

WF-1901

1. **Joanna Metzner-Sadurski, MD (4) - SC015 (MUSC MU)**
2. **Adedayo Onitilo, MD, PhD (2) - WI144, WI210 (WINCORP)**

WF-2201

1. **Christina Cramer, MD (5) - NC002**
2. **Michael Chan, MD (2) - NC002**

WF-2202

1. **Mary Helen Hackney, MD (4) - VA010 (VCU MU)**
2. **Ami Chitalia, MD (2) - DC007 (Capital MU)**
Michael Porrazzo, MD (2) - SC119 (MUSC MU)

WF-2301CD (Patient-Caregiver Dyads)

1. **Michael Humeniuk, MD (3) - SC101, SC024 (UPSTATE)**
2. **Hemchandra Mahaseth, MD (2) - CO034 (KAISER)**
Harsha Poola, MD (2) - WI212 (WINCORP)

Top CC Accruing Investigators

(from 10/01/2024 - 12/31/2024) Patient Accruals



Christina Cramer, MD
NC002 (5)



Mary Helen Hackney, MD
VA010, VCU MU (4)



Thomas Lad, MD IL042,
Stroger MU (4)



Joanna Metzner-Sadurski, MD
SC015, MUSC MU (4)

Top CDR Accruing Investigators

(from 10/01/2024 - 12/31/2024) Patient and Dyad Accruals



Andrew Huang, MD,
WI028, CROWN (3)



Michael Humeniuk, MD,
SC101, SC024, UPSTATE (3)

**Meet Wake Forest NCORP Research Base Staff: Renee
Glenn**



Renee has been with the Wake Forest NCORP Research Base for 7 years and with Wake Forest for 15 years. She works with the Regulatory team assisting with all regulatory aspects related to studies including NCI, CIRB and local IRB submissions as well as updating federal agencies such as CT.gov. Outside of work, Renee enjoys flower gardening, traveling and reading Jack Reacher books.

New Publications & Presentations

Manuscripts:

- **WF-1803CD Caregivers:** McLouth LE, Sterba KR, Snavely AC, et al. Breadth and Depth of Patient and Caregiver Supportive Services in Community Oncology (WF-1803CD). *Psychooncology*. 2024;33(12):e70034. doi:10.1002/pon.70034
- **WF-1804CD AH-HA:** Kepper MM, Gierbolini-Rivera RD, Weaver KE, et al. Multilevel factors influence the use of a cardiovascular disease assessment tool embedded in the electronic health record in oncology care. *Transl Behav Med*. Published online December 13, 2024. doi:10.1093/tbm/ibae058
- **WF-30917CD Telehealth:** Danhauer SC, Brenes GA, Weaver KE, et al. A multi-site feasibility study of a stepped-care telehealth intervention for depression and anxiety in post-treatment cancer survivors at community cancer clinics (WF-30917CD). *J Cancer Surviv*. Published online January 14, 2025. doi:10.1007/s11764-024-01721-0

Abstracts:

American Society of Preventative Oncology (ASPO)

- **WF-2202 SHINE:** Shaffer KM, Dressler EV, Glazer JV, et al. Recruitment Successes and Challenges for a National Cancer Institute Community Oncology Research Program Trial of an Internet-Delivered Sexual Health Intervention for Breast Cancer Survivors (WF-2202). ASPO Conference, April 6-8, 2025. Poster Presentation.
- **WF-2300CD CONNECT Survey:** Nightingale C, Levine B, Farris M, et al. Interest and Capacity among NCI Community Oncology Research Program (NCORP) Practices to Participate in a Lung Cancer Caregiver Intervention: Findings from WF-2300CD. ASPO Conference, April 6-8, 2025. Poster.

Health Equity Core Updates

On February 4th, 2025, Metro-Minnesota Community Oncology Research Consortium (MMCORC) had fifty-five team members participate in the *Just Ask*[™] training as part of our mandatory quarterly all-team meeting. MMCORC leadership dedicated time during the February meeting for our Community NCORP to utilize the *Just Ask*[™] program, a collaboration by the American Society of Clinical Oncology (ASCO) and the Association for Community Cancer Centers (ACCC) to establish practical strategies and solutions to help increase participation in cancer treatment trials by patients from historically underrepresented communities. Ahead of the training event, all team members completed the series of interactive modules available free online in preparation for the small group discussions including writing a short commitment to equity statement. The *Just Ask*[™] Training Facilitation Guide was essential for our planning group members from MMCORC's Inclusive Research Workgroup and MMCORC Community Outreach Core group who also hosted the event and were introductory speakers. After a rotation of small group discussions at tables of five led by a table facilitator designated ahead of time, we came together as a full group and shared common themes and strategies that emerged. The energy level in the room was enthusiastic and research teams are excited

to take the strategies developed back to their cancer centers to partner in building equity in clinical trial participation with the providers and the clinic cancer care teams.

Just ASK™ Background & Learning Objectives

The Just ASK™ program is a collaboration by the American Society of Clinical Oncology (ASCO) and the Association for Community Cancer Centers (ACCC) to establish practical strategies and solutions to help increase participation in cancer clinical trials by patients from historically underrepresented racial and ethnic communities.

Learning Objectives

1. Describe various dimensions of diversity that exist within society and the ways sociocultural norms shape perceptions
2. Explain how implicit bias shapes interactions and interrelates with health disparities
3. Identify strategies to address barriers to approaching underrepresented populations to engage in cancer clinical trials



The Wake Forest NCORP Research Base Health Equity Core focuses on recruitment & retention of minority/underserved populations. This group meets quarterly to share best practices, influence study design, discuss community engagement strategies and share resources and tools. If you are interested in joining this group, please contact us at

NCORP@wakehealth.edu

WF NCORP RB Quarterly Calls

Please [click here](#) to watch the recording of the January 29 Quarterly Call. The next call is scheduled for April 2, 2025.

[Click here to add the Quarterly Call to your calendar](#)

Recipe: Grapefruit & Honey Salmon



- 2 ruby red grapefruit
 - 1 1/2 tablespoons honey
 - Kosher salt and finely ground black pepper
 - 1 large shallot, finely chopped
 - 2 tablespoons extra-virgin olive oil
 - 3 cups fresh flat-leaf parsley leaves
 - Four 6-ounce skinless salmon fillets
1. Juice 1 grapefruit into a bowl. Cut the peel and pith from the other grapefruit. Remove the flesh from the membranes with a sharp knife, adding any juice to the juice in the bowl. Reserve the grapefruit segments.

2. Boil the reserved juice, honey and 1/4 teaspoon each salt and pepper in a small saucepan until reduced by half and slightly syrupy, 4 to 6 minutes.
3. Toss the grapefruit segments with the shallots, oil, parsley, 1/2 teaspoon salt and 1/4 teaspoon pepper.
4. Bring a large, straight-sided skillet with 4 cups of well-salted water to a simmer; the water should cover the salmon. Add the salmon to the skillet and remove from the heat. Let the salmon cook in the hot water until just cooked through, 5 to 7 minutes.
5. Transfer the salmon to paper towels and pat dry. Place on serving plates. Drizzle the salmon with the sauce and top with the grapefruit salad.

Recipe from: [Food Network](#)



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