



## STUDY MATTERS

---

March 13, 2025

Wake NCORP Website: <https://wakencorp.phs.wakehealth.edu/>

### \*\*\*REMINDER\*\*\*

Current Good Clinical Practice (GCP) certification is required for access to our REDCap database. GCP certification dates in RSS always default to the 1st of the expiration month. If you receive a notice from REDCap about your account expiring this is most likely due to an expiring GCP certification. You can upload new certificates to our website (<https://wakencorp.phs.wakehealth.edu/>) or you can email them to [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

---

### Upcoming Site Calls

If you haven't already added the meeting to your calendar, click the button below the meeting to add it now.

**\*\*Please note that your calendar may not update automatically if changes are made. Please check these emails and our website for meeting updates.\*\***

You can also join site calls from our [Wake NCORP website](#). Click the call in the "Upcoming Events" section on the Home page or through the Calendar. You must be a registered user to join from the website.

If you are having trouble joining a call or have any other issues please email [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu)

**WF-1805CD - HN-STAR - Implementation and Effectiveness Trial of  
HN-STAR**

**Wednesday, March 19 3:00-3:30 pm ET**

**WF-2301CD - CONNECT - Multi-site Community Oncology Planning  
for the CONNECT Intervention Targeting Lung Cancer Caregivers**

**Thursday, March 20 3:00-3:30 pm ET**

**Quarterly Call**

**Wednesday, April 2 3:00-4:00 pm ET**

**Study Updates**

**WF-1805CD - HN-STAR - Implementation and  
Effectiveness Trial of HN-STAR**

**Step 1 Participant Enrollment in OPEN is closed.**

All Step 2 enrollments and DC visits must be completed by April 14, 2025. Any participant who cannot complete their Step 2 enrollment and DC visit by April 14 must be withdrawn from the study.

**Thank you for helping us enroll to this important study!**

If there are any questions regarding WF-1805CD, we are glad to help. Please contact us at [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu); Attn: WF-1805CD.

---

## **(NEW!)WF-1806 - M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer**

### **NEW SPANISH DOCUMENT POSTED**

**WF-1806 (M&M) Amendment 10, Protocol Version Date 12/30/2024, Release Date 02/24/2025**

The Spanish version of the following document was posted on CTSU on Friday, February 28, 2025. Please implement this version within 30 days of this post.

- **Consent Form, (PVD 12/30/24): Spanish**

**Previously approved Spanish versions of the patient assessments have not been updated with this amendment and will remain in force.**

1. CARE Questionnaire\_v05.01.20\_Spanish
2. Demographic and Health Behaviors\_v05.01.20\_Spanish
3. Hand-Grip Physical Test\_v05.01.20\_Spanish
4. Life-Space Survey\_v05.01.20\_Spanish
5. Short Physical Performance Battery Protocol\_v05.01.20\_Spanish
6. NCI PRO-CTCAE Items\_v05.01.20\_Spanish
7. GP5\_v04.01.21\_Spanish
8. Was It Worth It Questionnaire\_v11.08.21\_Spanish

---

**WF-1806 (M&M) Amendment 10, Protocol Version Date 12/30/2024, Release Date 02/24/2025:**

The WF-1806, *Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer (M&M)* study has been amended. The amended protocol and related documents were released on **Monday, February 24, 2025**. The changes and documents within this amendment must be implemented within 30 days of this posting.

**Changes with this amendment include:**

- Updated the location where CT scan DICOM images will be sent.
- Administrative changes to grammar and language for clarification.

**\*See Helpful Guidelines v.02.24.2025 for new details regarding mailing DICOM images. A new version of the FAQs dated 02.24.2025 has also been posted\***

**WF-1806 Document Access:**

- The protocol and participant directed documents are available on the [CTSU](#) website.
- The *Helpful Guidelines*, *FAQs*, *Provider Fact Sheet* and *Training Attestation* documents are available on the [WAKENCORP](#) website.

If there are any questions regarding WF-1806 we are glad to help. Please contact us at [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu); Attn: WF-1806.

## **WF-2304-A172401 – COSMIC - Complementary Options for Symptom Management in Cancer**

**WF2304-A172401 COSMIC – Revised Study Summary Now Available**

**COSMIC - WF2304-A172401 PtMtl Study Summary, version date 02.06.2025, aligned with COSMIC (WF2304-A172401) Amendment 1, Protocol Version Date 11/19/2024, Release Date 01/15/2025.**

The revised study summary was posted to CTSU website on 02/26/2025. "**Small cell lung cancer**" has been corrected to read "**non-small cell lung cancer**".



## Study Summary (WF2304 - A172401)

The COSMIC Study wants to understand how patients with cancer manage their cancer-related symptoms during treatment.

### Why should I be in this study?

- Many patients with cancer have bothersome symptoms that are related to their cancer, and even the medicines they take. Patients often use different ways to help alleviate the symptoms.
- The COSMIC Study wants to understand the potential risks and benefits of the approaches that patients use. Examples include therapies such as acupuncture or meditation, the use of cannabis, dietary supplements, and many others.

For your participation in the COSMIC study, you can receive \$10-\$20 for each monthly survey you complete.

### What will I have to do?

- You will be asked to fill out a short survey to see if you are eligible.
- If you are eligible for the study, you will be asked to be in the study for about 13 months and complete the following surveys:
  - Baseline survey
  - 12 monthly surveys (1 per month for 12 months)
- Every survey is done electronically and is confidential. Your responses will not be shared with your medical team.



Taking part in this study is your choice and you may change your mind at any time.

## Study Summary (WF2304 - A172401)



### Who will take part in this study?

Adults aged 18 and older who:



- Are currently being treated for a newly diagnosed cancer of the following type: breast cancer, colorectal cancer, melanoma, non-Hodgkin lymphoma, or non-small cell lung cancer.
- Have not started treatment or are in the early stages of treatment.
- Are willing to be in the study for 13 months and complete an electronic survey each month.
- Are receiving medical care from a community oncology clinic.

### What is the cost of taking part in this study?

All costs related directly to the study will be paid for by the study. The costs of your regular medical care are unrelated and fall under your existing coverage. The study does not cover your personal internet or cellular data usage charges.



### How can I learn more?

- Visit [The COSMIC Study](#) or scan the QR Code to the right with your smartphone camera.
- Call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237)
- For general cancer information, visit the NCI website at [www.cancer.gov](http://www.cancer.gov)



<Insert local site contact information here>

If there are any questions regarding WF2304-A172401 please

contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) Attn: WF2304-A172401. To request printed copies of recruitment materials, please use the WF2304-A172401 Recruitment Request survey: <https://redcap.link/WF2304-A172401.RecruitmentMaterials>

---

## TRAVEL AWARD COMPETITION

Our Research Base will be offering a travel award to one site for each of the following studies: WF-1806 (M&M) , WF-1901 (IMPACTS) and WF-2301CD (CONNECT). The travel award will be given to the sites with the most enrollment between January 1st, 2025 – July 31, 2025, one award per study. This award will help cover expenses up to \$1000 for travel to the 2025 Wake Forest NCORP Research Base Annual Meeting in Asheville, North Carolina!

---

## Wake Forest NCORP Research Base Website

**Reminder:** Additional resources, **which are not CIRB approved**, are maintained on our Wake Forest NCORP RB website and **are not available on CTSU**. Note, these resources include a **Helpful Guide** for each study, which provides guidelines for the study team, as well as other study instructions.

**\*Remember to update your profile to include any new studies you may be involved in\***

We use this information for targeting email communications and surveys.

<https://wakencorp.phs.wakehealth.edu/>

Registering for an account will allow you to:

- Join site calls and other meetings from the Upcoming Events or Calendar sections
- Access study training materials
- View previous study meetings

- Download important study documents including training videos, study guides, and neurocognitive CRFs

**Once registered, you must update your user profile to sign up for study-specific mailing lists and meeting announcements, indicate your NCORP Community site, add your user roles, and update your GCP for database access.**

If you have any questions or need assistance with registration, please email [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

---

## Accruals as of March 12, 2025

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	239	+1	300		
WF-1901	IMPACTS	211	+4	250	12	40
WF-1805CD	HN-STAR	349	+6	350	135	140
WF-2201	HYPOGRYPHE	23	+3	244		
WF-2202	SHINE	334	+9	336		
WF-2301CD	CONNECT	34 (pt/ caregiver dyad)	+4	120 (dyads)		
WF2304-A172401	COSMIC	113	64	2000		
		Practices Enrolled	Change in past 2 weeks	Target (practices)	Enrolled (non-patients)	Target (Non-Patients)
WF-2303CD	HRSN	15	+1	20	48	136