



*Advancing Research. Improving Lives.™*

## **NRG-CC012CD "SYMON"**

**Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment**

16 October 2025  
Practice Personnel Update

**Presenters:**

**Dr. Alla Sikorskii, Jamillah Gross-Caldwell**

This NRG-Oncology protocol is being conducted in collaboration with NIH/NCI R01 #1R01CA279472-01 funding to Drs. Sikorskii MPI (contact), Badger (MPI) and Crane (MPI).



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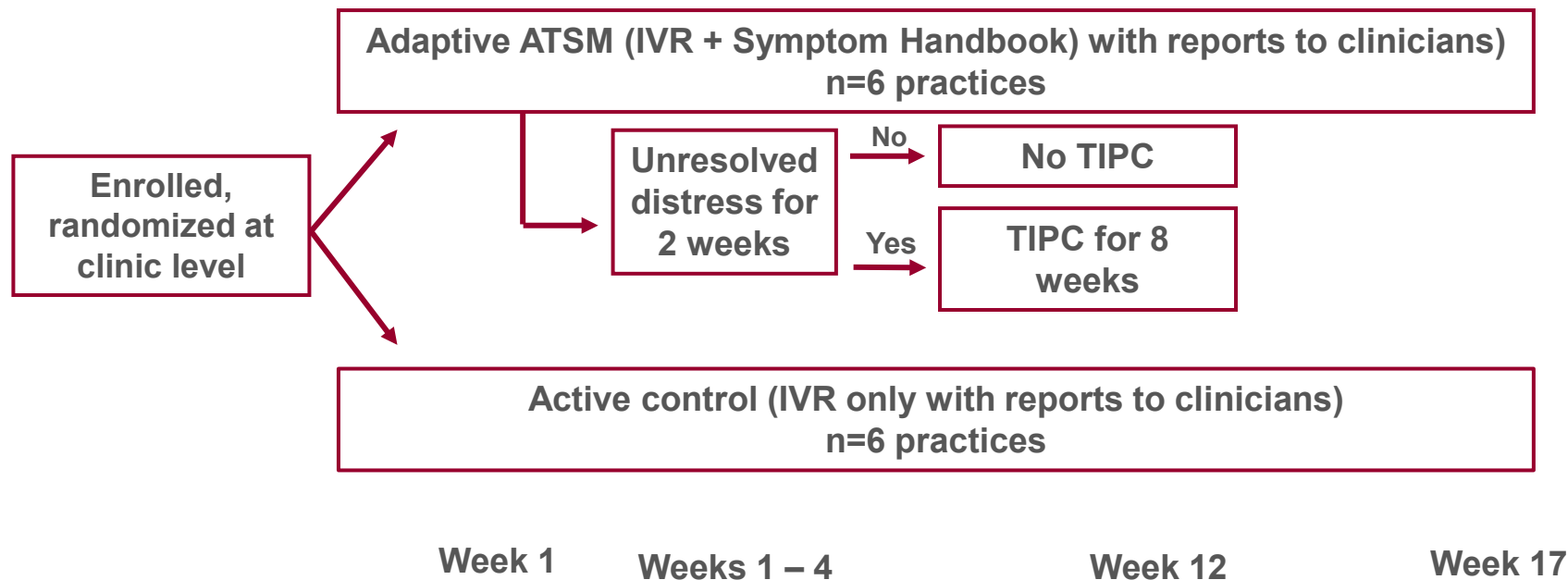
# Study Team

<u>Principal Investigator</u>  <b>Alla Sikorskii, PhD</b> Michigan State University	<u>Co-Chair, Health Disparities</u>  <b>Terry Badger, PhD, RN,</b> <b>PMHCNS-BC, FAPOS, FAAN</b> University of Arizona	<u>Co-Chair, Patient Reported Outcomes</u>  <b>Tracy Crane, PhD, RDN</b> University of Miami
<u>Co-Chair, Nursing</u>  <b>Melyssa Foust, MSN, RN</b> Upstate Carolina NCORP	<u>NCORP Community Co-Chair</u>  <b>Vamsi Krishna Vasireddy, DO</b> Carle Cancer Institute	<u>Statistician</u>  <b>Stephanie Pugh, PhD</b> NRG Oncology
<u>SWOG Champion</u>  <b>Virginia Sun, PhD, RN</b> City of Hope	<u>Alliance Champion</u>  <b>Kelly A. Hirko, PhD, MPH</b> Michigan State University	

# Contacts

<p><b>Data Management</b> For questions concerning eligibility or data submission</p>	<p><b>Lisa Abate</b> abatel@nrgoncology.org</p> <p><b>Aaron Johnson</b> johnsona@nrgoncology.org</p>
<p><b>Protocol Development</b> For questions concerning protocol and informed consent versions &amp; amendments</p>	<p><b>Erica Field, MPH, MHA</b> fielde@nrgoncology.org</p>
<p><b>Project Managers</b> For questions concerning patient recruitment, data collection, and intervention delivery.</p>	<p><b>Jamillah Gross-Caldwell, MSU</b> 517-353-6534</p> <p><b>Grey Freylersythe, UMiami</b> 305-243-9832</p> <p><b>Shared Inbox:</b> symon@miami.edu</p>

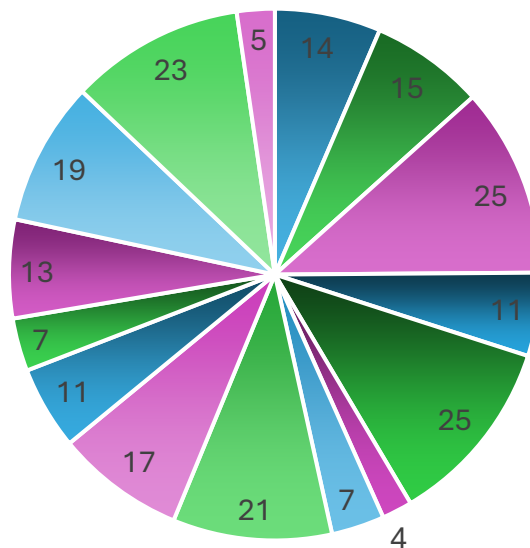
# Participant Intervention



# Progress

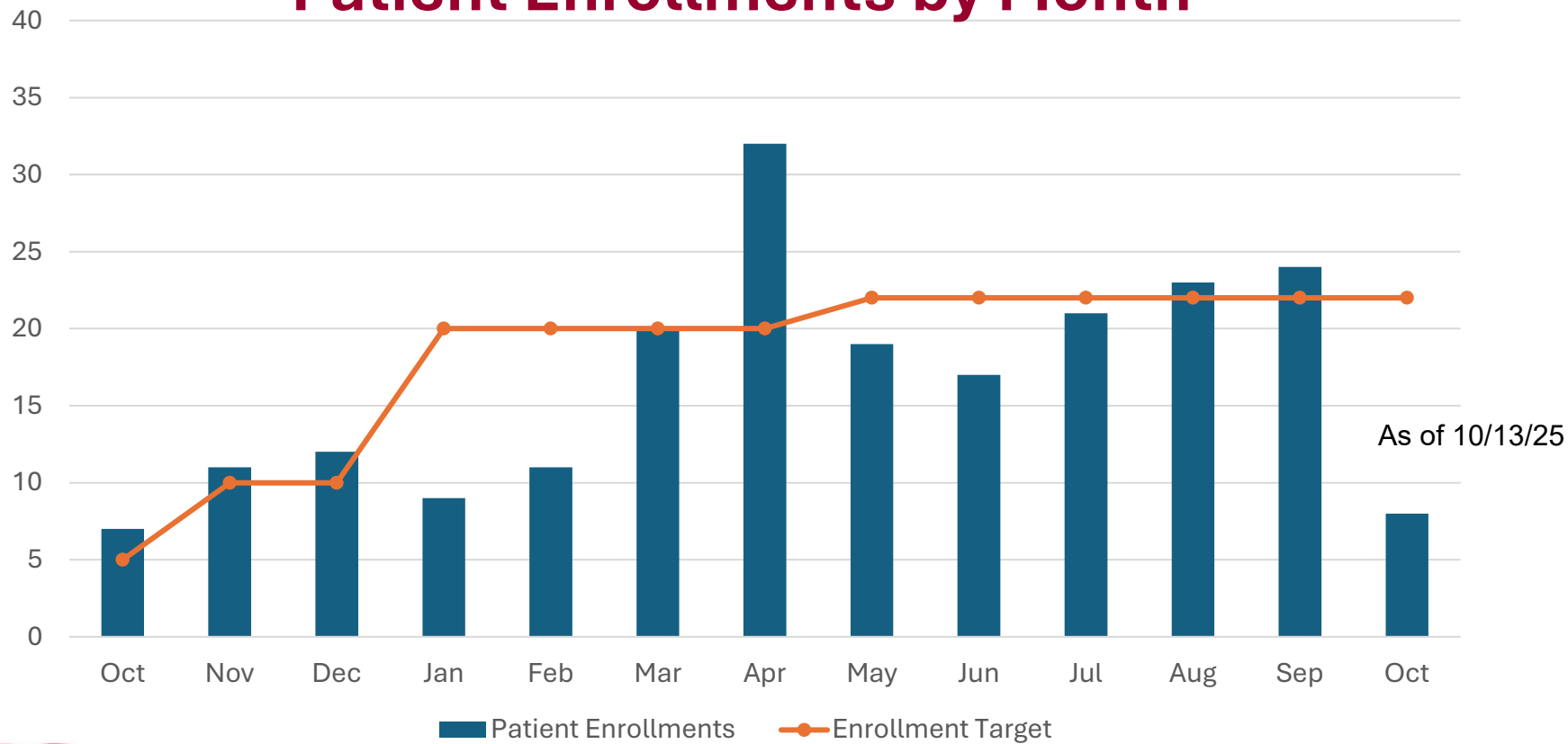
- Protocol activation 5/20/24
- Opened to patient accrual 10/4/24
  - N= 218 patients enrolled (as of 10/13/2025)
  - Top enrolling site – new site taking the lead: Georgia Cares n=25!
  - Special shout out to Lake Regional Ozarks, still highest enrolling single site with n=21!
  - Two newest sites have started strong with enrollments in past two months: Hawaii n=5 and MUSC n=7
- 15 sites enrolled
  - N=7 IVR “Control”, N=8 ATSM “Intervention”
  - 11 of 12 Rural-qualified practices
  - N=50 nonpatients enrolled (as of 9/16/2025)

**Patient Enrollments  
as of 10/13/25**



- AR020
- AZ151
- GA020, GA040, GA105
- IL042
- IL168, IL393, IL405, IL406
- KS114 (CLOSED)
- LA029
- MO200
- NM004
- PR046, PR050, PR031, PR030
- SC008
- SC045, SC053, SC036, SC060
- SC064
- WI028, WI093, WI128, WI146, WI176, WI219
- HI005, HI023, HI027, HI046, HI051

# Patient Enrollments by Month



# Spanish Speakers Enrollment

- Progress on 15% Spanish Speaking Goal (78/516 Total Patients)
  - 6 Practices have >10%+ Spanish Speakers (SS)
    - One site, Puerto Rico, has 99%.
  - 9 Practices have <10% Spanish Speakers
  - YTD Total Spanish Speaking Enrollments: **27**
  - YTD SS% of Total Enrollment: **13.7%**

# CTSU Updates

- 10/13/2025
  - No Updates
  - Coming Soon – updated PCF

**NRG-CC012CD “SYMION”  
Patient Contact Information Form**

Consent Date: \_\_\_\_\_

Site ID: \_\_\_\_\_

Patient ID: CC012CD- \_\_\_\_\_

Patient Name \_\_\_\_\_

Patient Address \_\_\_\_\_

Patient Preferred Language (select one): English ☐ Spanish ☐

Patient Phone Number \_\_\_\_\_ Cell ☐ Landline ☐

Patient Alternate Phone Number \_\_\_\_\_ Cell ☐ Landline ☐

Preferred Days and Times for Interviews:

Day of the week \_\_\_\_\_ Time (local, include time zone) \_\_\_\_\_

Preferred Days and Times for IVR Calls:

Day of the week \_\_\_\_\_ Time (local, include time zone) \_\_\_\_\_

Name of oral anti-cancer medication(s) that qualified patient to participate in the study  
\_\_\_\_\_

Instructions:

1. Complete within 24 hours of patient registration in OPEN
2. When complete, email with encryption security to [symon@miami.edu](mailto:symon@miami.edu)

Form completed by (select all that apply):

☐ Patient

☐ Staff





# Reminders and Questions

## Recent FAQs

*NRG-CC012CD FAQs are posted on CTSU (v.4.15.2025)*

# Vital Status Reports in RAVE

- Vital Status Reports in Rave
  - Calendar-based date is only an estimate
    - This date is set to a max of 10 days after registration, and the real date will depend on when baseline can be completed (potentially weeks later, dependent upon patients answering and having started the oral agent).
  - Weeks should align, even if dates don't.
    - The week 1 vital status should be completed when the first symptom report is received from Miami. Ideally, within 1 week of due date.
  - There is flexibility in the dates, up to 2 weeks is okay.
    - If > 2 weeks, contact [symon@miami.edu](mailto:symon@miami.edu) to request for NRG to update the calendar-based date.

# Participant Withdrawal

- Email [symon@miami.edu](mailto:symon@miami.edu) to notify Miami so that we can stop calls. We don't get Rave notifications automatically.
- Submit the following forms in Rave so that NRG knows to cancel future data collection
  - Off Study Form
  - Withdrawal of Consent Form

# Learn More

- **Contact us!**

- Jamillah Gross-Caldwell & Grey Freylersthe  
**SYMON@miami.edu**

- **Resources**

- General information:
  - [www.craneresearchlab.org/cc012cd](http://www.craneresearchlab.org/cc012cd)
    - Monthly Update slides will be posted here after each monthly meeting
    - Sample recording of symptom monitoring call uploaded now
  - [www.nrgoncology.org/Clinical-Trials/Protocol/nrg--cc012cd?filter=nrg--cc012cd](http://www.nrgoncology.org/Clinical-Trials/Protocol/nrg--cc012cd?filter=nrg--cc012cd)
- NRG Meeting Kick-Off Training
  - [nrg2024winter.s3.amazonaws.com/RG-CC012CD+Workshop.mp4](https://nrg2024winter.s3.amazonaws.com/RG-CC012CD+Workshop.mp4)





Questions?

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