



*Advancing Research. Improving Lives.™*

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

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

March 2026

Practice Personnel Update

**Presenters:**

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

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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NRG Oncology

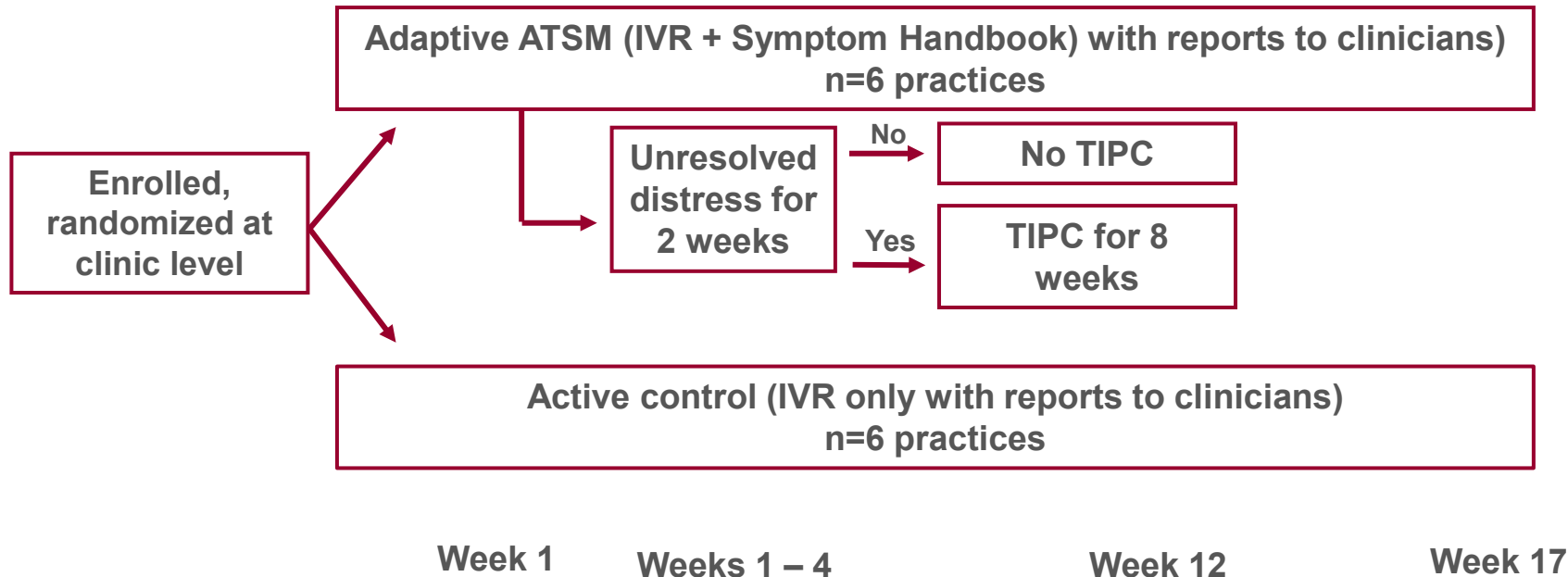
# Study Team

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

# Contacts

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

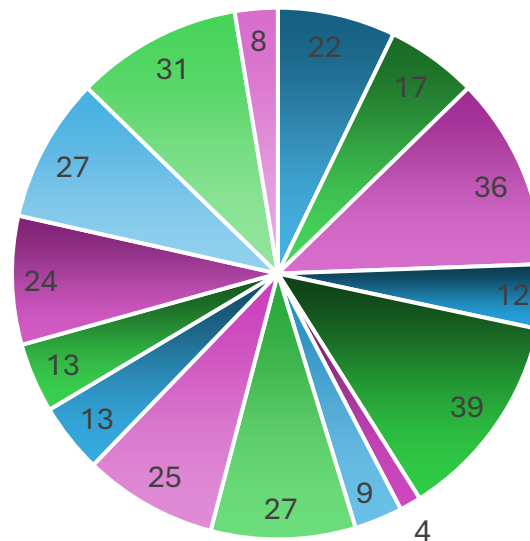
# Participant Intervention



# Progress

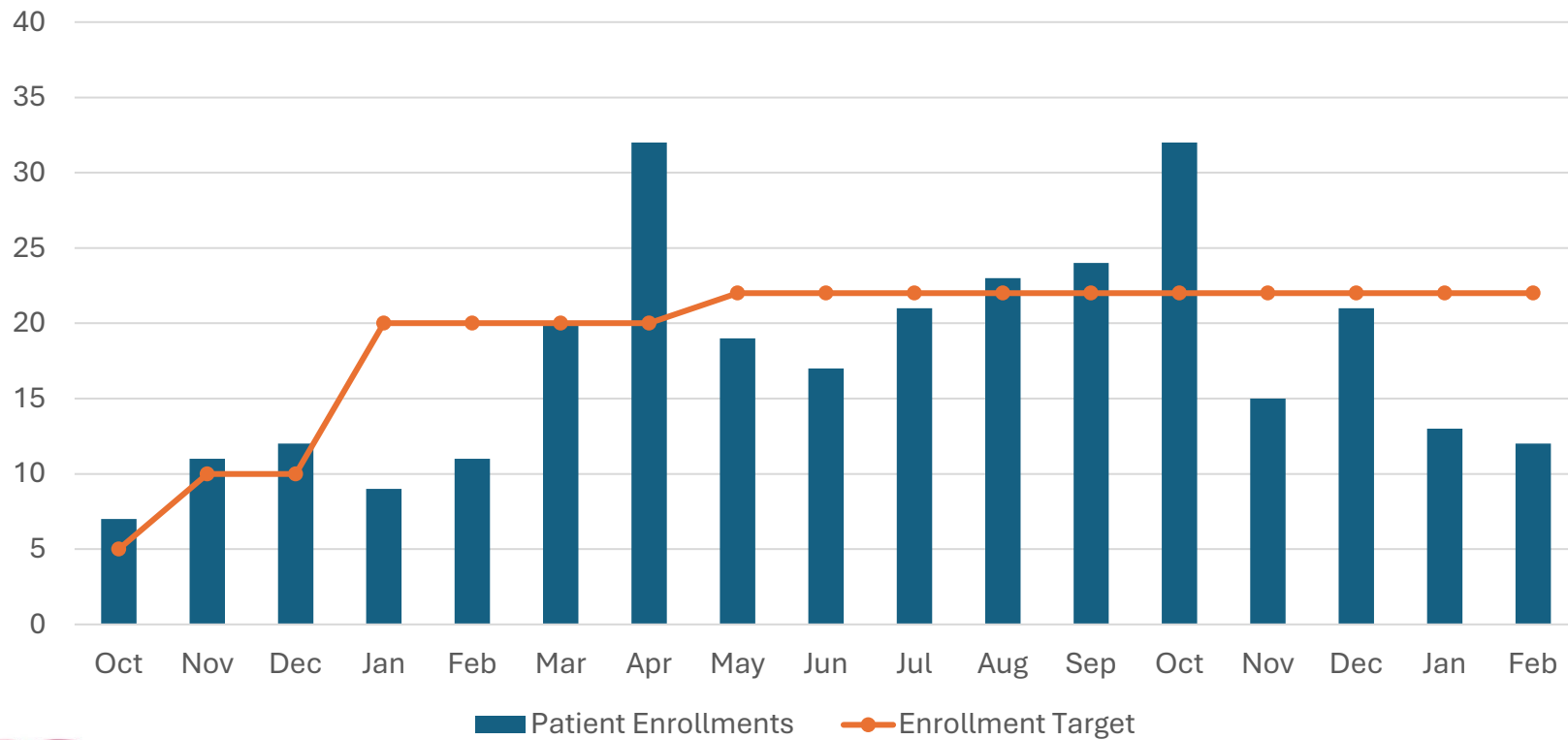
- Protocol activation  
5/20/24
- Opened to patient  
accrual 10/4/24
- Current Accruals (as of  
2/28/26)
  - PATIENTS N= 307 / 516  
(59%)
    - Lake Regional Ozarks  
(MO200) and Anmed  
Upstate Carolina (SC064)  
tied for highest enrolling  
single site (27)
    - Carle highest enrolling  
multi-site (39)
  - PERSONNEL N=56 / 50

Patient Enrollments  
as of 2/28/26

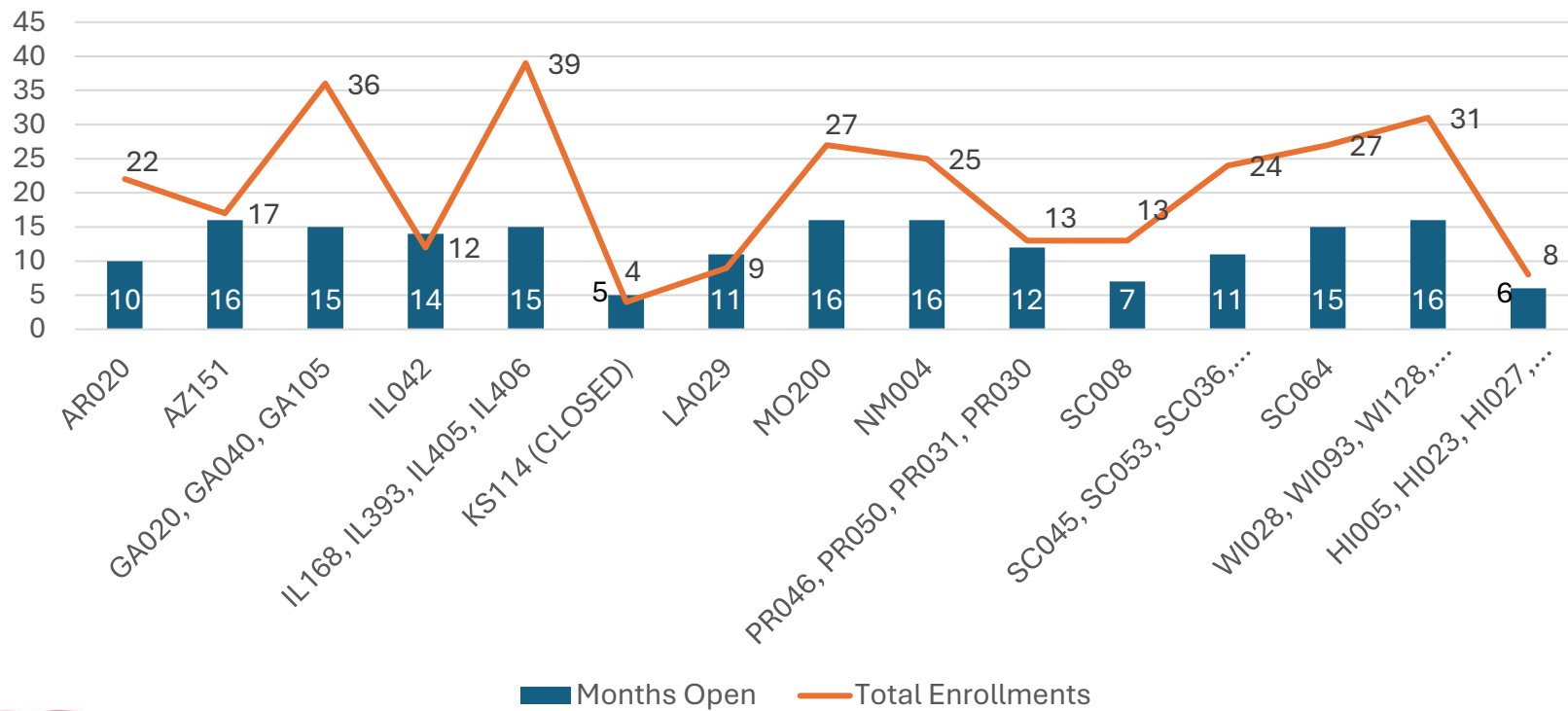


- AR020
- AZ151
- GA020, GA040, GA105
- IL042
- IL168, IL393, IL405, IL406
- KS114 (CLOSED)
- LA029
- MO200
- NM004
- PR046, PR050, PR031, PR030
- SC008
- SC045, SC053, SC036, SC060
- SC064
- WI028, WI093, WI128, WI146, WI176, WI219
- HI005, HI023, HI027, HI046, HI051

# Patient Enrollments by Month



# Patient Enrollments by Site



# Spanish Speakers Enrollment

- Target 15% Spanish Speakers (N=78/516)
  - Total Spanish Speaking Enrollments: N=35/78 (44.9%)



# Reminders and Questions

# 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 45 days after registration now!!
    - Note: the real start 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.
    - Week 1 can be up to 2 weeks different from calendar-based start date. If >2 weeks, email [symon@miami.edu](mailto:symon@miami.edu) and provide the following information:
      - » **Subject #: CC012CD-00XXX**
      - » **Original Calendar Base Date: 6/30/2025**
      - » **Requested change to Calendar Base Date: 7/30/2025**

# Upcoming Amendments

Correction to protocol Section 5.1 at next amendment to clarify language

- **Recruitment of patients.** Eligible patients will be identified by recruiters at the practice as those within 8 weeks after starting a new oral agent or about to start a new oral agent within the next 4 weeks.
- (Section 3.6.1 is accurate)

# 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 Freylersythe  
[SYMON@miami.edu](mailto: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](http://nrg2024winter.s3.amazonaws.com/RG-CC012CD+Workshop.mp4)





Thank you!



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THE UNIVERSITY  
OF ARIZONA