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## NRG-CC012CD "SYMON"

Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment

December 2025  
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



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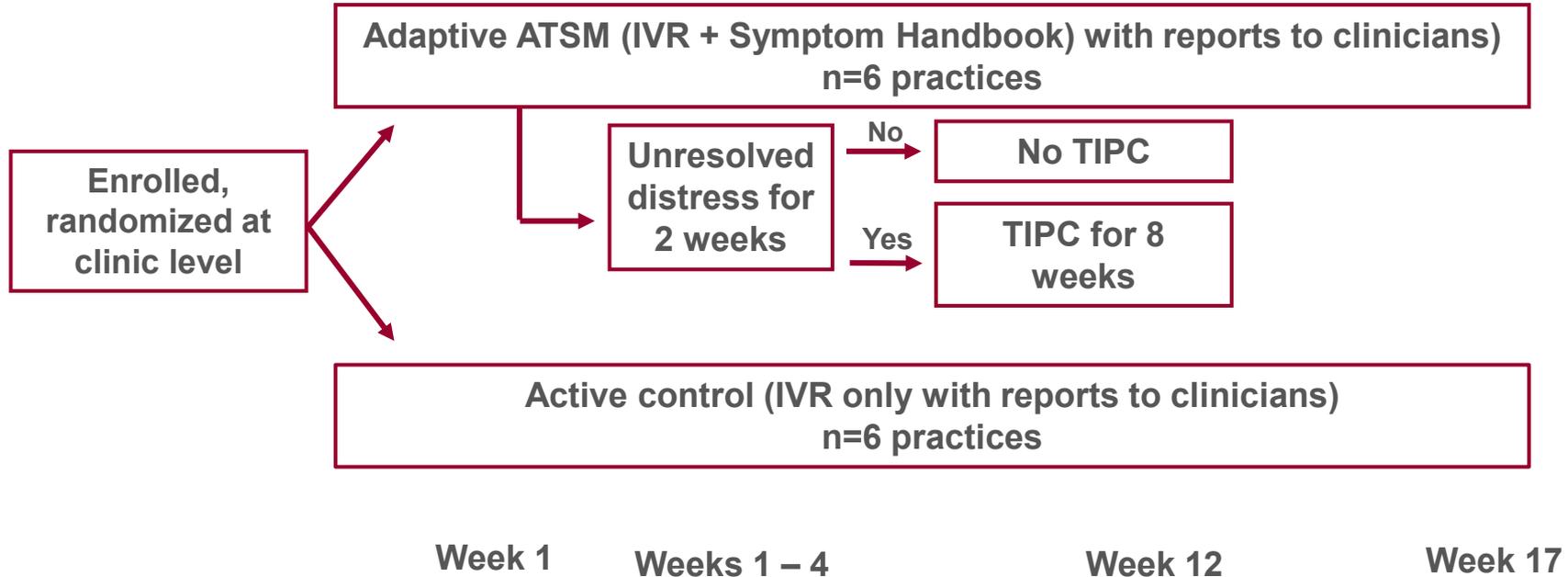
# Study Team

<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

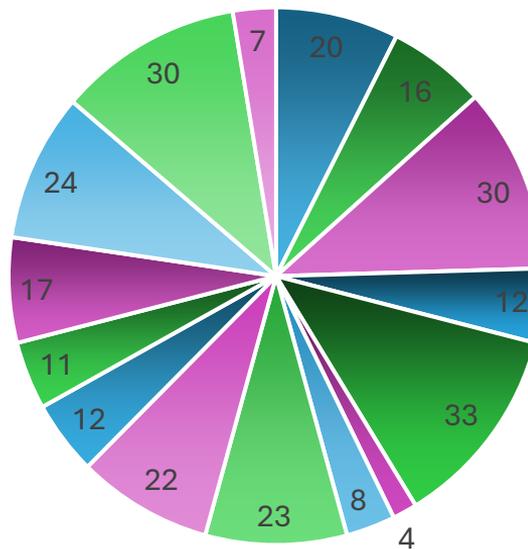
# Participant Intervention



# Progress

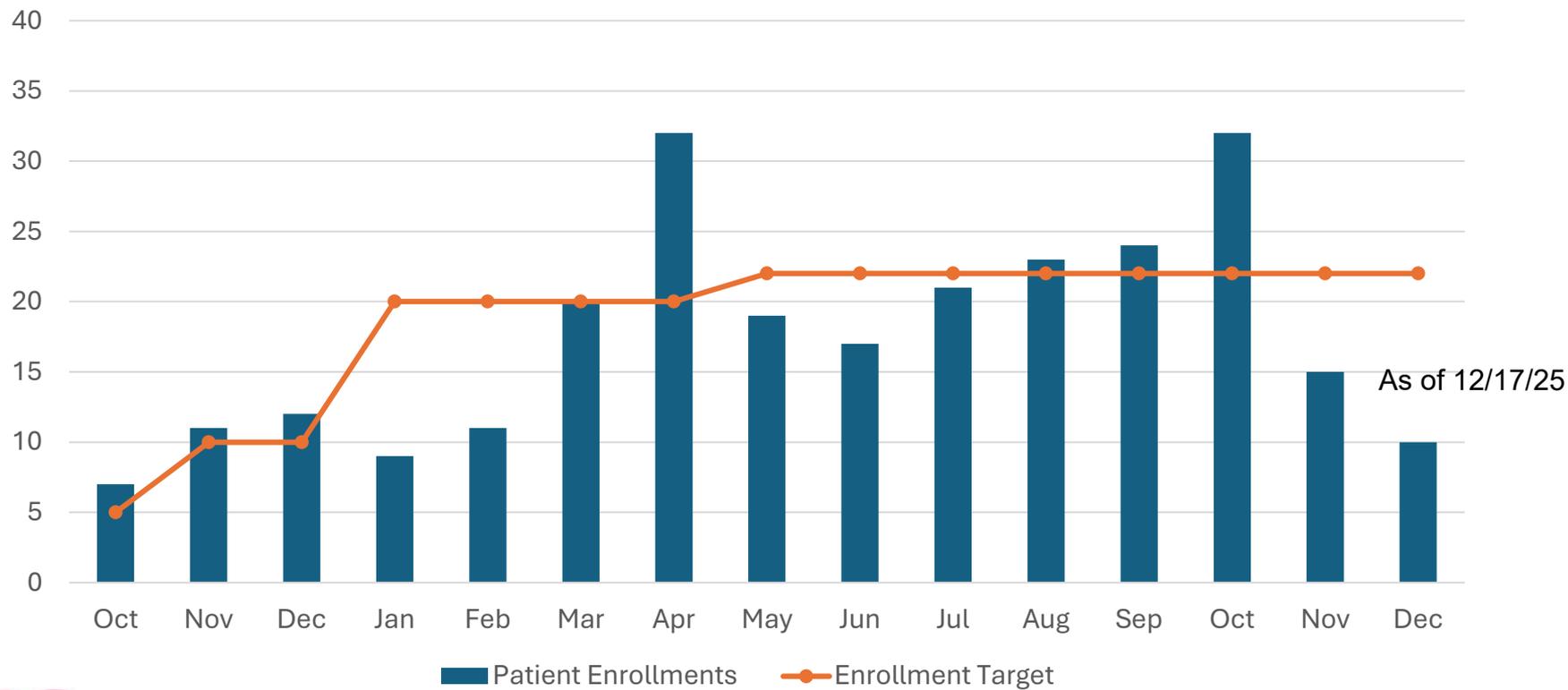
- Protocol activation  
5/20/24
- Opened to patient  
accrual 10/4/24
- Current Accruals  
(12/17/25)
  - N= 269 / 516 (52%)
    - Top enrolling site – Carle!
    - Special shout out to Lake Regional Ozarks, **still** highest enrolling single site with n=23!

Patient Enrollments  
as of 12/17/25

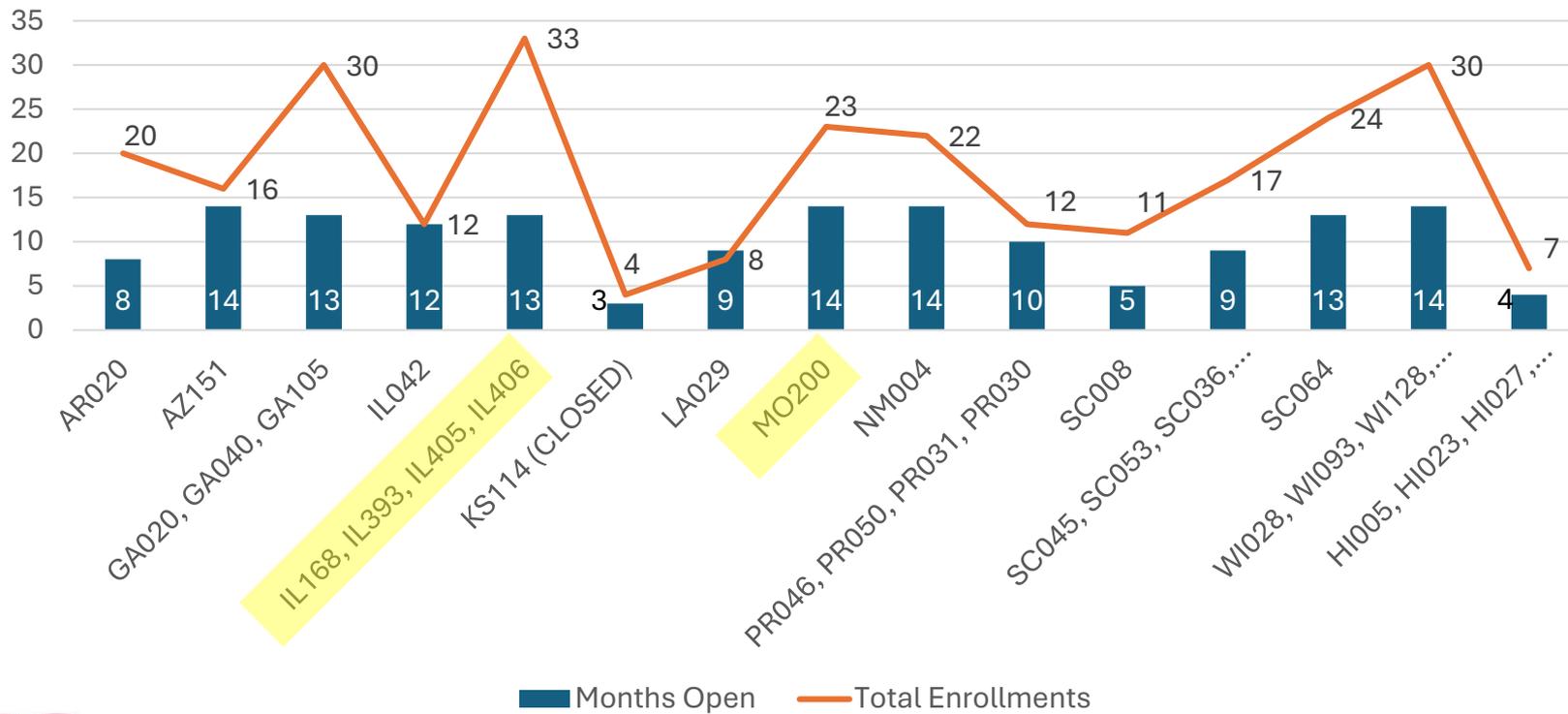


- AR020
- AZ151
- GA020, GA040, GA105
- IL042
- IL168, IL393, IL405, IL406
- KS114 (CLOSED)
- LA029
- MO200
- NM004
- PR046, PR050, PR031, PR030
- SC008
- SC045, SC053, SC036, SC060
- SC064
- WI028, WI093, WI128, WI146, WI176, WI219
- HI005, HI023, HI027, HI046, HI051

# Patient Enrollments by Month



# Patient Enrollments by Site



# Spanish Speakers Enrollment

- Target **15%** Spanish Speakers (N=78)
  - 6 Practices have >10%+ Spanish Speakers (SS)
    - One site, Puerto Rico, has 99%.
  - 9 Practices have <10% Spanish Speakers
- Enrollment to Date
  - YTD Total Spanish Speaking Enrollments: **37**
  - YTD SS% of Total Enrollment: **14.4%**

# CTSUS Updates

- Please download and begin using updated Patient Contact Form
- Now includes name of oral agent to help interviewers at baseline

**NRG-CC012CD "SYMÓN"  
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

# 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

# Reminder – Monthly Reports

- Months 1-25 “Actions Taken” are due for IVR Report Recipients
  - There is also a TIPC feasibility monthly report
- Months 1-25 Recruitment report: numbers of screened, eligible, approached; reasons for ineligibility or refusal; and any issues encountered with recruitment.

In the past month, did you review summary reports of patient’s symptoms or take actions on patient symptoms?

No to both

Yes, reviewed summary symptom report

Yes, took actions on symptoms (actions based on the report or otherwise)

1. For each patient on the study in the past month, please check the actions you took and time in minutes it took you to complete them.

Patient ID, all weeks in the past month	Action	Time in minutes to complete action	Practice personnel involved in action
ID1	Ordered to schedule symptom-related office visit(s)		
	Completed symptom-related office visit(s) or televisit(s)		
	Ordered changes in oral agent dosing or oral agent stoppage		
	Prescribed medications to relieve symptoms		
	Referred patient to supportive care services (pain management/palliative care, behavioral health)		
	Other (describe)		
ID2 (repeat)			

# Practice Personnel Data Collection

Begin watching Rave for Practice Personnel 12-month forms!

\*\*Additional 20 questions for TIPC Interveners at sites

Questionnaire	# Questions
Attitudes Toward Symptom Management (BL, 12 and 25 months)	11 questions
Feasibility of Intervention Measure (FIM) for Automated Telephone Symptom Monitoring (12 and 25 months)	12 questions
Feasibility: Planning for Change (12, and 25 months)	4 questions
Acceptability of Intervention Measure (AIM) for the automated telephone symptom monitoring (12 and 25 months)	4 questions
Acceptability of Intervention Measure (AIM) for TIPC (months 12 and 25)	4 questions
Intervention Appropriateness Measure (IAM) for automated telephone symptom monitoring (months 12 and 25)	4 questions
Intervention Appropriateness Measure (IAM) for TIPC (months 12 and 25)	4 questions

# Similar/Competing Studies

- **CA204-008 PREAMBLE** (Prospective Research Assessment in Multiple Myeloma): Co-enrollment is allowed, because it is an observational study
- **EAQ221CD CONCURxP** (Medication Adherence): Sites with this trial open should offer the CONCURxP protocol first, and then SYMON can be offered to participants who decline the first.
- **EQA222CD CostCOM** (Financial Navigation): Co-enrollment is allowed, because it is not a symptom-specific intervention
- **COSMIC WF2304-A172401** (Cannabis Cohort): Co-enrollment is allowed, because COSMIC is observational.
- **NRG-CC015** (HEAL-ABC Mindfulness): Not competing. Breast cancer patients on this protocol must be 6 months post-treatment completion, so would not be eligible for SYMON.

# 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](https://nrg2024winter.s3.amazonaws.com/RG-CC012CD+Workshop.mp4)





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from all of us!**



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