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NRG-CC012CD "SYMON"

Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment

**20 November 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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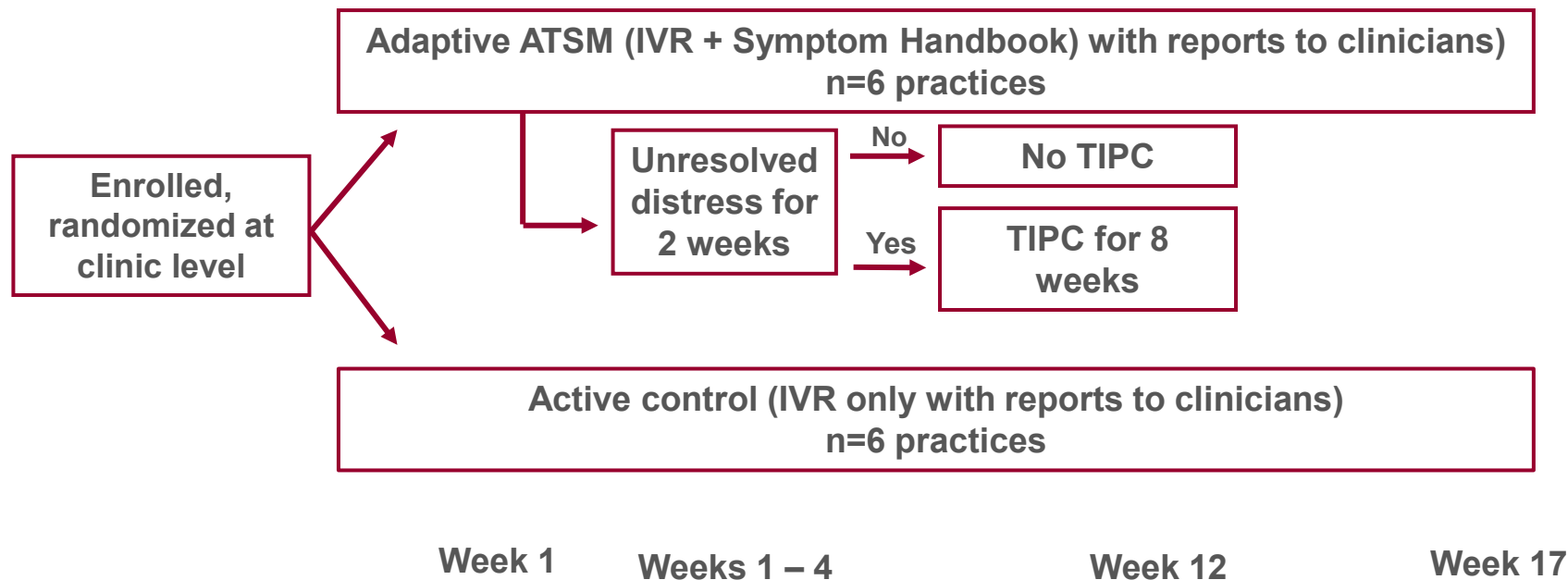
Study Team

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

Contacts

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

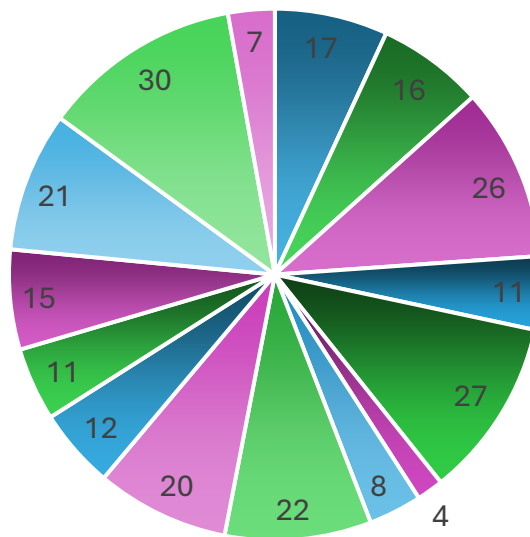
Participant Intervention



Progress

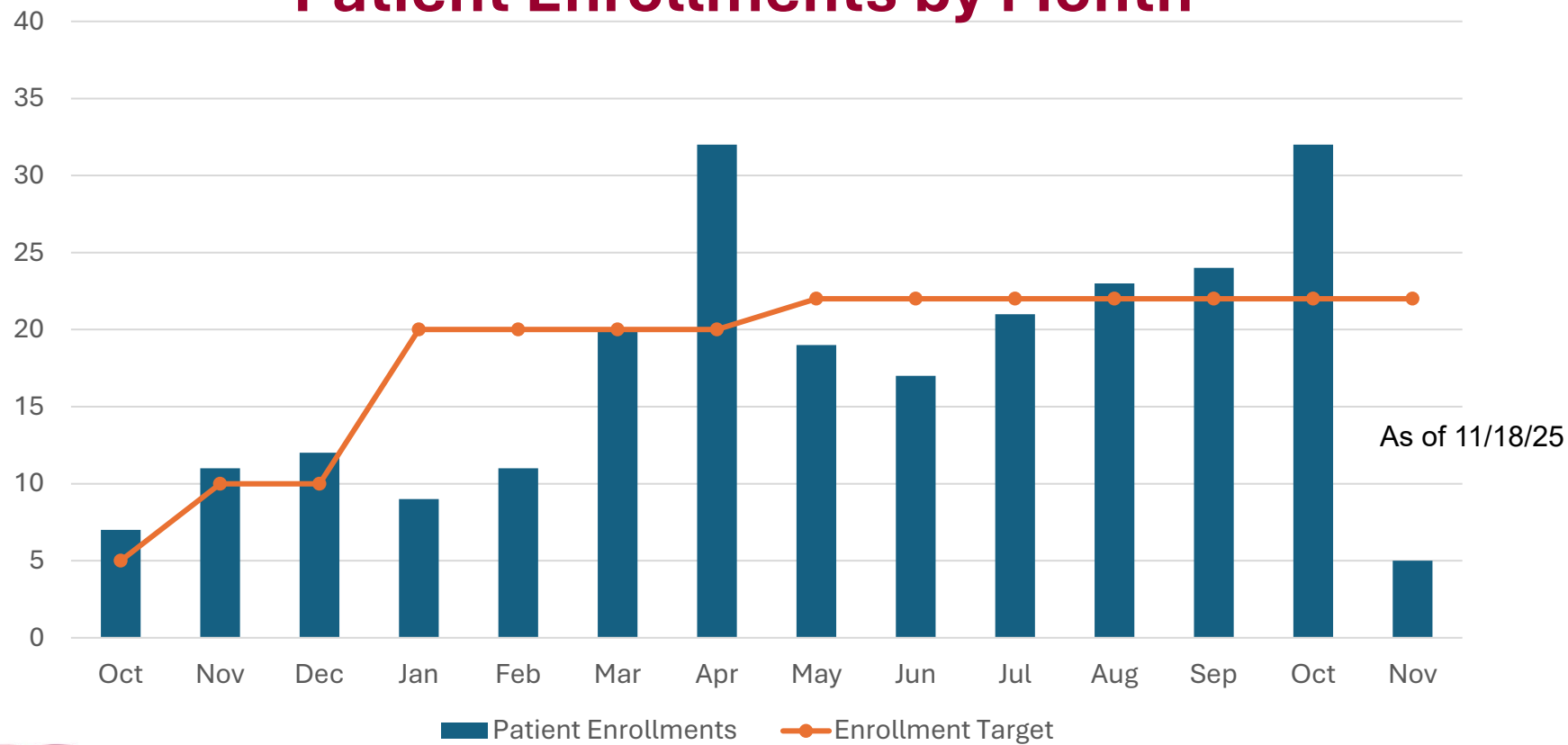
- Protocol activation 5/20/24
- Opened to patient accrual 10/4/24
 - N= 247 patients enrolled (as of 11/18/2025)
 - Top enrolling site – Aspirus CROWN
 - Special shout out to Lake Regional Ozarks, **still** highest enrolling single site with n=22!
- 15 sites enrolled
 - N=7 IVR “Control”, N=8 ATSM “Intervention”
 - 11 of 12 Rural-qualified practices
 - N=53 nonpatients enrolled (as of 10/31/2025)

**Patient Enrollments
as of 11/18/25**



- 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

- 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: **34**
 - YTD SS% of Total Enrollment: **14.2%**

Intervention/TIPC Updates

- Telephone Interpersonal Counselling
 - Only for clinics in ATSM/Intervention randomization arm
 - Delivered by behavioral health specialist, social worker, etc.
 - Site versus study-provided
 - Initiated in weeks 1-4, 8-week duration
 - Centralized calls through My Wellness Research® for monitoring and fidelity
- TIPC Referrals to Date
 - Anmed Upstate Carolina (n=1)
 - Carle (n=1)

CTSU Updates

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

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

Form completed by (select all that apply):

- ☐ Patient
- ☐ Staff



Reminders and Questions

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)

- 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

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 to request for NRG to update the calendar-based date. Provide the following information:
 - » Subject #: CC012CD-00XXX
 - » Original Calendar Base Date: 6/30/2025
 - » Requested change to Calendar Base Date: 7/30/2025

“Discontinuation of Medication”

This is a common reason reported by participants for not answering our calls. We leave voicemails but unless we speak to them, we won't know why they aren't answering. We are not able to text/email.

Solutions? Suggestions?

Participant Study Completion

- You will receive an email from Jamillah when your participant has completed their Week 17 interview/final study activities. We also notify NRG.
- Usually we start trying to complete Week 17 around the same time as the IVR, but with preferred times/scheduling it may take 2-3 weeks to complete.

Participant Withdrawal

- Email 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
 - 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
- NRG Meeting Kick-Off Training
 - nrg2024winter.s3.amazonaws.com/RG-CC012CD+Workshop.mp4





Questions?

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