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NRG-CC012CD "SYMON"

Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment

26 June 2025

Practice Personnel Update

Presenters:

Dr. Alla Sikorskii, Jamillah Gross-Caldwell, Grey Freylersythe

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).

Study Team

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

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See protocol for complete contact details

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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

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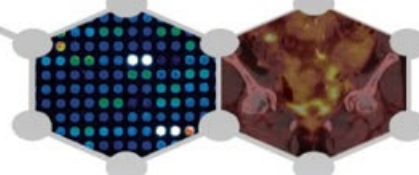
See protocol for complete contact details



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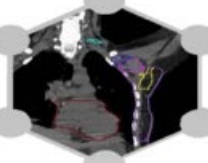

Study Updates

CTSU Updates

Administrative amendment approved 6/16/2025

Document	Details	CTSU Post Date
Protocol	Amendment 3 • Adding new sites/practices (12+ or 6+ per arm) • Sample size – overall sample the same (516) but site-specific max increased to 45 • Minor changes to report recipients and general language	6/23/25
Consent Forms - PATIENT	• Adding study phone number and caller ID	6/23/25
Recruitment Scripts	• Language clarifications and adding study phone number/caller ID	6/23/25

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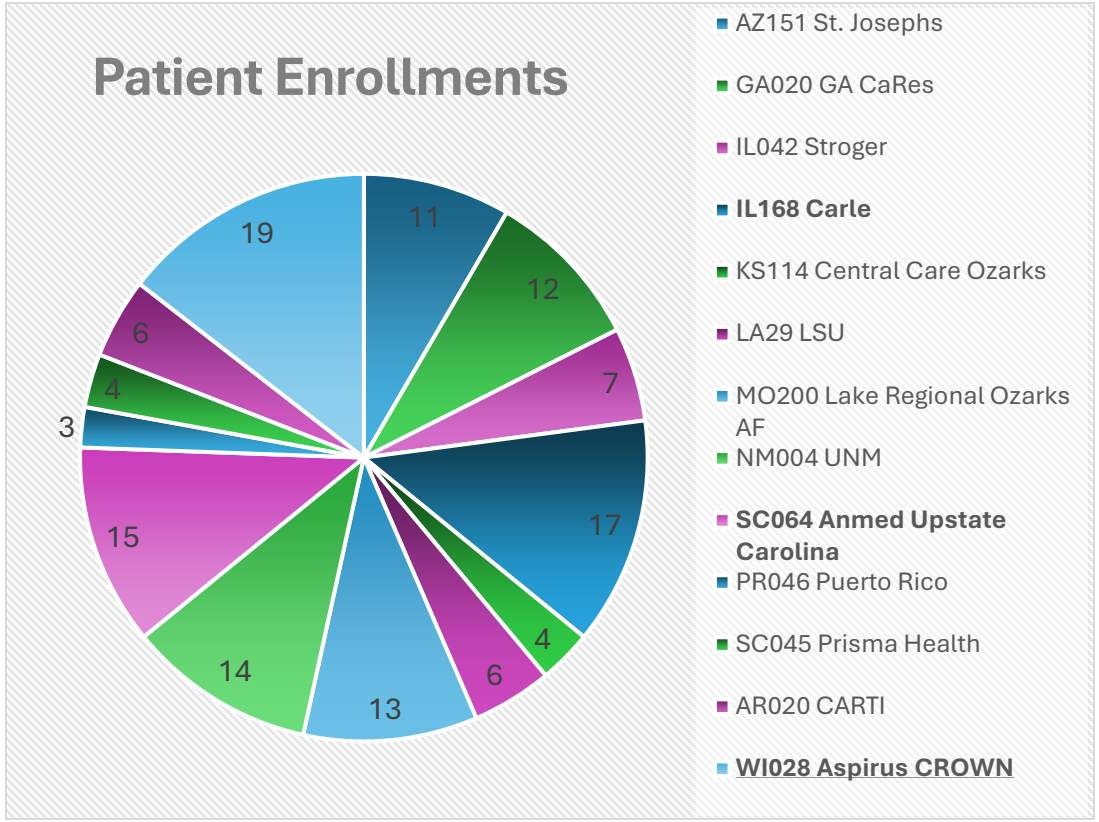
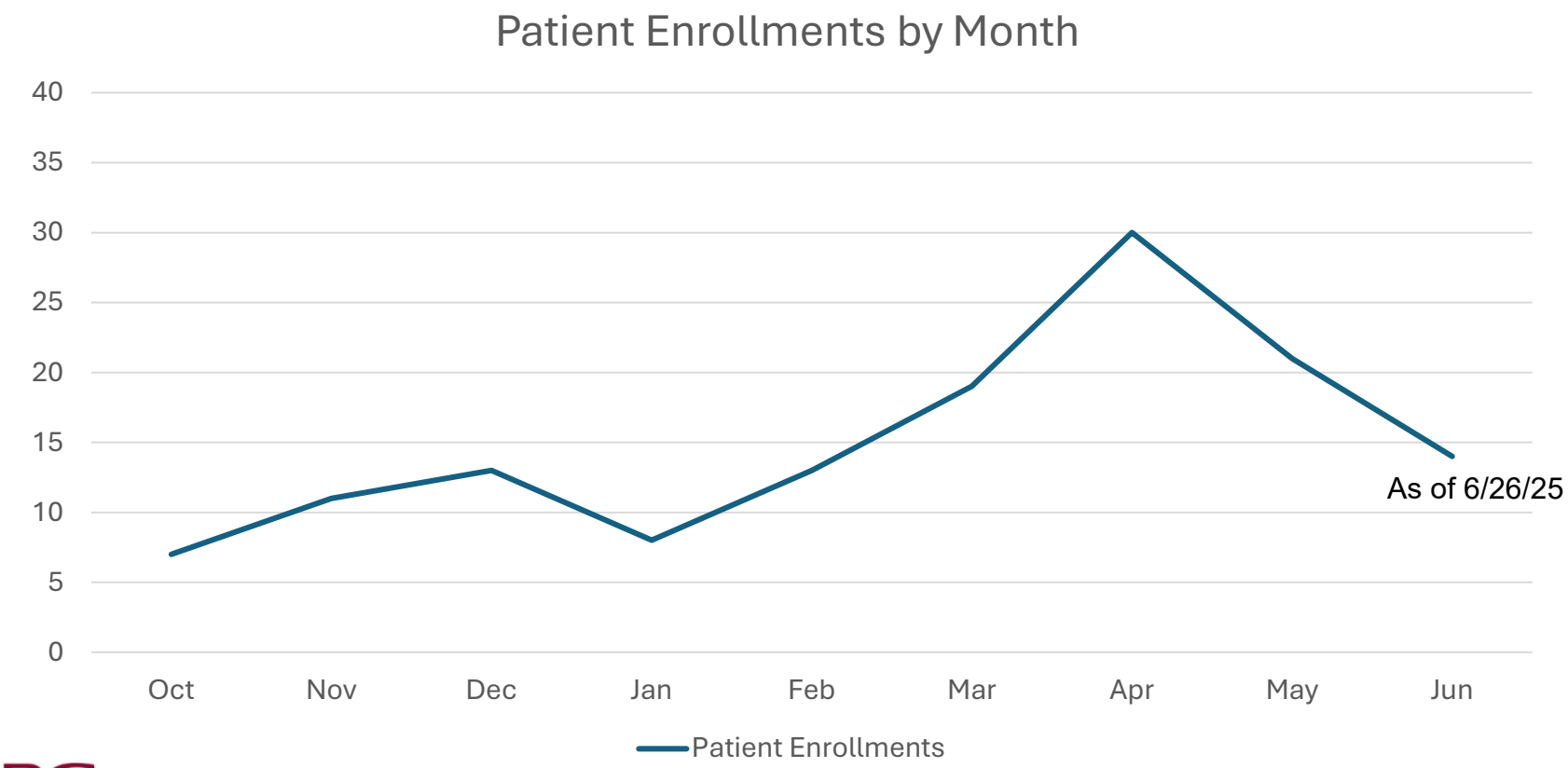
Progress

- Opened to patient accrual 10/4/2024
- N=137 patients enrolled (as of 6/26/25)
- 15 sites enrolled
  - 2 new sites – Welcome!
    - University of Hawai'i Cancer Center/Queens Medical Center
    - Medical University of South Carolina/Hollings Cancer Center





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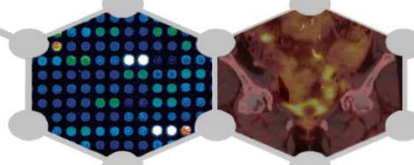

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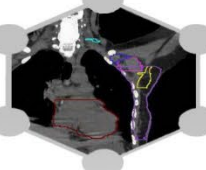

Brief Study Overview

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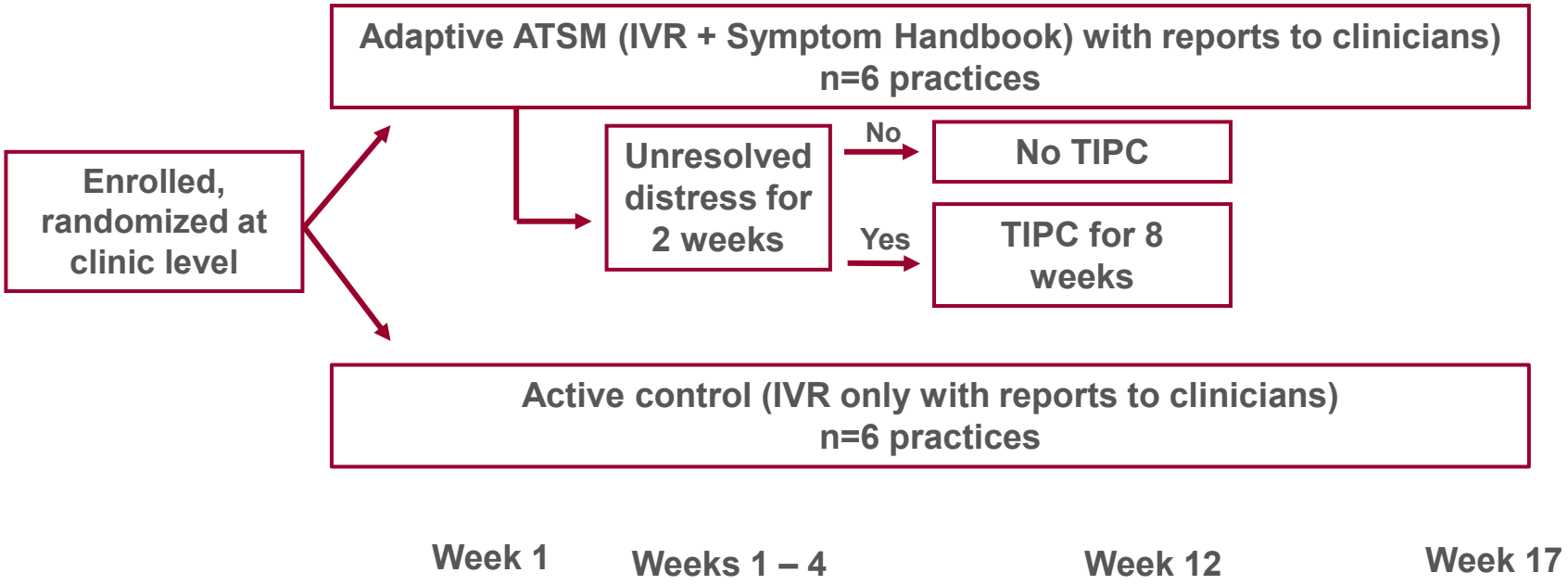
Participant Intervention



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IVR = Interactive Voice Response
ATSM = Automated Telephone System Management
TIPC = Telephone Interpersonal Counseling

Review of Practice Study Activities

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Practice Personnel Eligibility Criteria

Practice personnel are key stakeholders in this research study. They will:

- Consent to participation
- Complete baseline demographic information form
- Complete baseline questionnaire about symptom management
- Receive symptom reports
- Complete brief monthly "actions taken" checklist
- Complete assessments at months 12 and 25

Eligible: physicians, nurses, nurse practitioners, advanced practice providers, physician assistants, medical assistants, pharmacists, etc.

- Planned to be involved in usual care for at least one enrolled patient during patient's participation in the study.
- At least one practice personnel has to agree to receive IVR reports and complete monthly forms (about 30 minutes). Multiple people can receive these reports.

Can be as few as **one** person or as many as applicable, ideally ~4

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Patient Key Eligibility Criteria

- Starting a new course of an oral anti-cancer agent within the next 4 weeks of registration or have started an oral agent within the past ~~4~~ **8** weeks (as of Protocol V2).
  - The list of agents is always posted to the CTSU website, but if an agent in question is not on that list, please email symon@miami.edu if you have questions
  - Can be receiving sex hormone inhibitor in *conjunction* with other oral anti-cancer agent
  - **Can** be receiving treatment with immune checkpoint inhibitor at enrollment (as of Protocol V2)
  - All concomitant medications and supportive care treatments are acceptable.
- Cannot be receiving *only* sex hormone inhibitor treatment
- Cannot be receiving competing supportive care:
  - Cannot be in any other symptom monitoring/management programs or studies
  - Cannot have had 2+ counseling/therapy sessions in past month for mood/psychosocial wellbeing
- Cannot be in hospice at time of enrollment
- Must be able to speak and understand English or Spanish.
- Must have access to a telephone with a touchpad and ability to hear a recording

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Recruitment – Tips and Best Practices

Refer to the Recruitment Script (Control or Intervention) for additional notes

- Update posted this week 6/23/2025

Notes

- Patients will participate for 17 weeks
- Patients will:
  - Receive 3 phone calls for interviews by study staff (baseline, week 13, and week 17)
  - Receive weekly *automated* phone calls for all 17 weeks to report their symptoms using their keypad
- Some patients may also receive TIPC with a behavioral health specialist for 8 weeks if:
  1) they are enrolled by an ATSM+IVR site and
  2) they report elevated emotional distress for two consecutive weeks in the first 4 weeks of the study
- Calls will be coming from: 888-602-8325 (Caller ID: MWR UMIAMI SYLV)
  - This is now added to ICF so they can take it with them
  - This can be added to a patient's phone contact list if that helps.
  - Patients can call this number, but it is a voicemail only line. They will not reach a human directly! They can also send us a text message.

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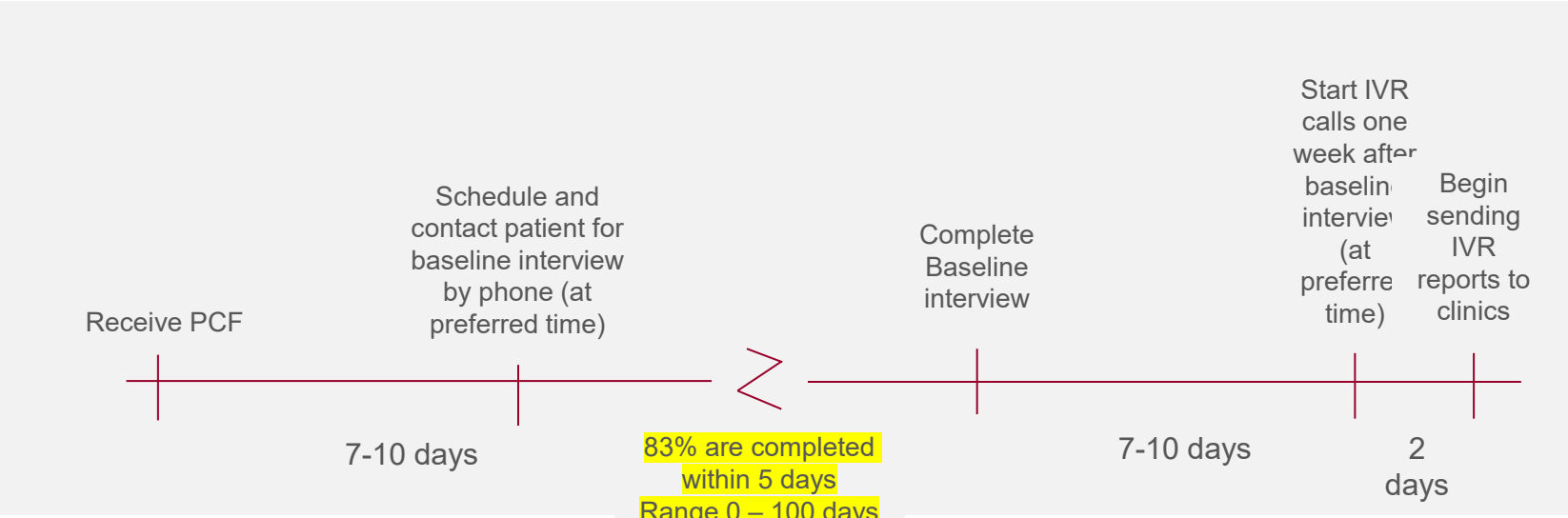
Timeline



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Next Month's Meetings

- Monthly practice personnel update - 7/17
- NRG Summer Meeting - 7/23-7/25

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Discussion Notes from Today

- If your patient withdraws from the study, please email symon@miami.edu to notify Miami so that we can stop calls. We don't get Rave notifications automatically.

- 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.

Learn More

- **Contact us!**
  - Jamillah Gross-Caldwell & Grey Freylersythe

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

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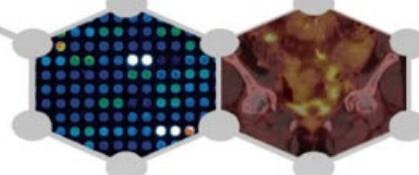

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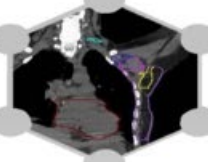

Questions?

UNIVERSITY OF MIAMI

MICHIGAN STATE UNIVERSITY

THE UNIVERSITY OF ARIZONA