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NRG-CC012CD "SYMON"

Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment

**May 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> 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



Study Updates

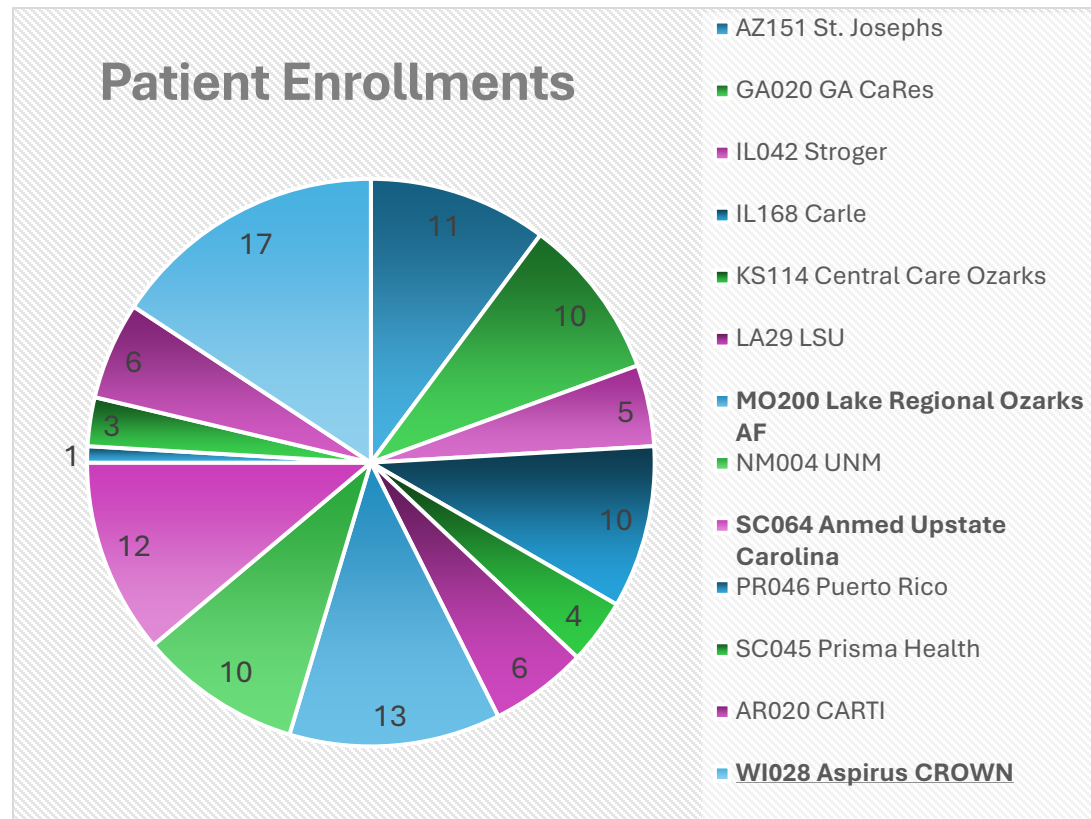
- No updates for May
- See table for April updates

CTSU Updates

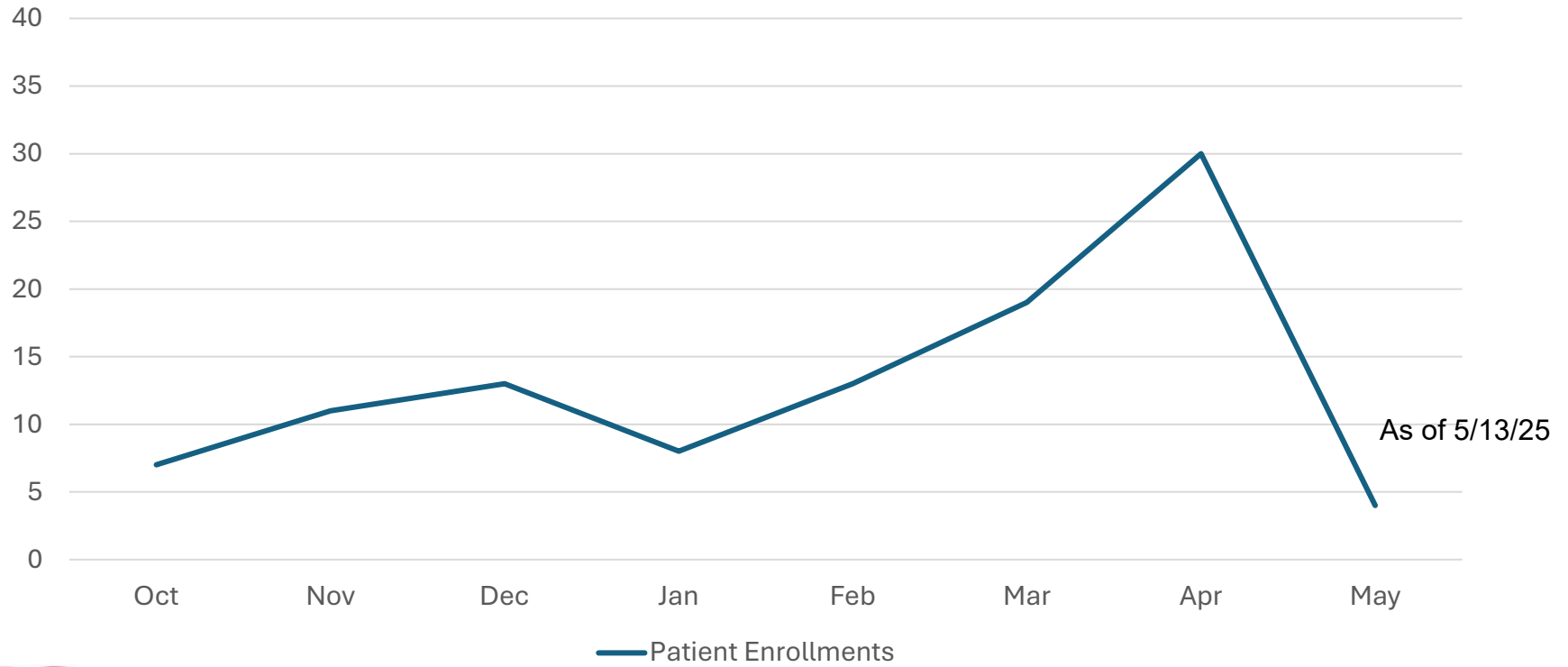
Document	Details	CTSU Post Date
Protocol	Amendment 2 Key changes impacting recruitment: - Immune checkpoint inhibitors are now included - Eligible window after initiation of oral agent extended from 4 weeks to 8 weeks	3/31/25
Consent Forms	English, Groups 1,2, Practice Personnel	3/31/25
	Spanish, Groups 1,2	4/2/25
Patient Brochure	English	3/31/25
	Spanish	3/27/25
Patient History Form	English	3/31/25
	Spanish	3/27/25
Practice Personnel Surveys		3/31/25

Progress

- Opened to patient accrual 10/4/2024
- N=106 patients enrolled (as of 4/16/25)
- 13 sites enrolled
 - 1 replacement site onboarded
 - All 13 sites enrolling patients!



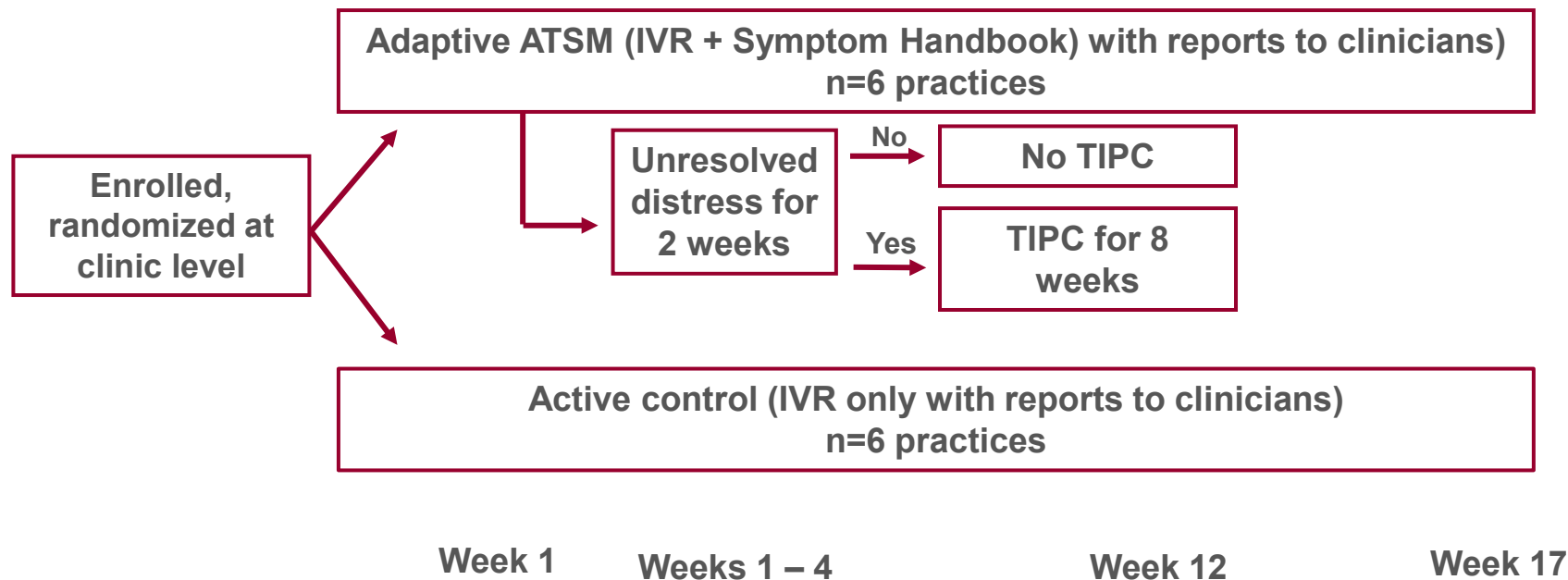
Patient Enrollments by Month





Brief Study Overview

Participant Intervention





Review of Practice Study Activities

Practice Personnel Eligibility Criteria

Practice personnel will be key stakeholders in this research study, themselves consenting to participation, receiving reports, and completing brief monthly questionnaires. The practice personnel must provide study-specific informed consent prior to study entry.

Eligible: physicians, nurses, nurse practitioners, advanced practice providers, physician assistants, medical assistants, pharmacists and **are involved in symptom management of patients on trial.**

- 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 receive IVR reports and complete monthly forms (about 30 minutes)

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

If applicable – if site has behavioral health professional who will deliver TIPC intervention, they must have licensure or eligibility for licensure in behavioral counseling if required by the State or Territory.

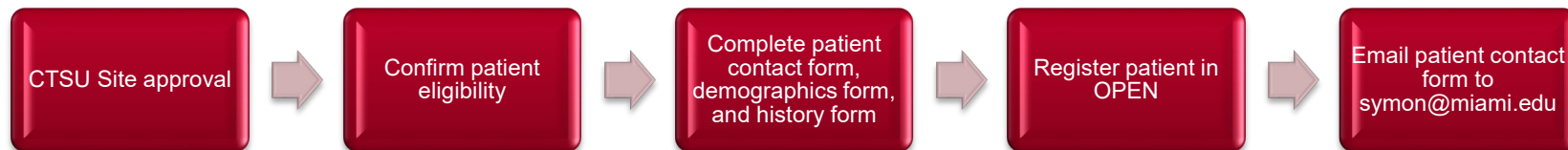
Patient Key Eligibility Criteria

- Must be starting a new course of an oral anti-cancer agent (the list of agents is always posted to the CTSU website), within 4 weeks of registration.
 - 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 competing supportive care treatments:
 - 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

Patient Enrollment

Plan to enroll 2 patients per month on average

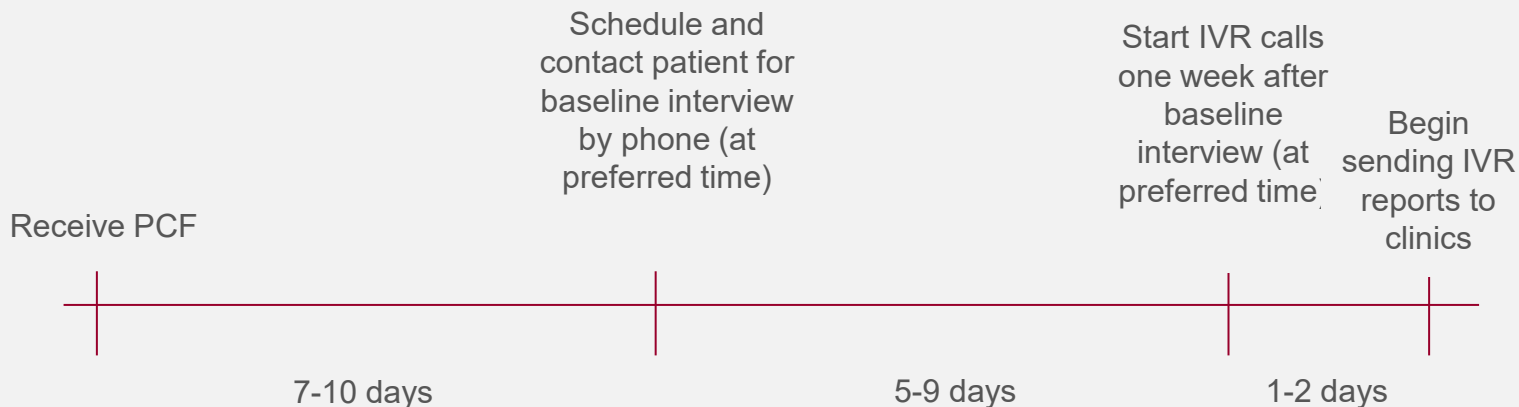
Process:



Key Recruitment 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)

What happens between patient enrollment and beginning to receive IVR reports each week for your patients?



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





Questions?

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