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

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

December 19, 2024  
Practice Personnel Update

Presenters:

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).

**NRG**



# Study Team

<p><b><u>Principal Investigator</u></b></p> <p><b>Alla Sikorskii, PhD</b>            Michigan State University</p>	<p><b><u>Co-Chair, Health Disparities</u></b></p> <p><b>Terry Badger, PhD, RN,            PMHCNS-BC, FAPOS, FAAN</b>            University of Arizona</p>	<p><b><u>Co-Chair, Patient Reported Outcomes</u></b></p> <p><b>Tracy Crane, PhD, RDN</b>            University of Miami</p>
<p><b><u>Co-Chair, Nursing</u></b></p> <p><b>Melyssa Foust, MSN, RN</b>            Upstate Carolina NCORP</p>	<p><b><u>NCORP Community Co-Chair</u></b></p> <p><b>Vamsi Krishna Vasireddy,            DO</b>            Carle Cancer Institute</p>	<p><b><u>Statistician</u></b></p> <p><b>Stephanie Pugh, PhD</b>            NRG Oncology</p>
<p><b><u>SWOG Champion</u></b></p> <p><b>Virginia Sun, PhD, RN</b>            City of Hope</p>	<p><b><u>Alliance Champion</u></b></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> 517-884-7662  <b>Grey Freylersythe, UMiami</b> 305-243-9832  <b>Shared Inbox:</b> symon@miami.edu



# Study Updates

# Protocol Amendment

Amendment 1 – PVD 10/31/2024

- Protocol and English ICFs - Posted to CTSU 11/18
- Spanish ICFs – Posted to CTSU 11/25
- Only change to protocol was to list each of the recruiting sites; ICF only updated to reflect the new PVD

Recruitment script – updated 11/25/24

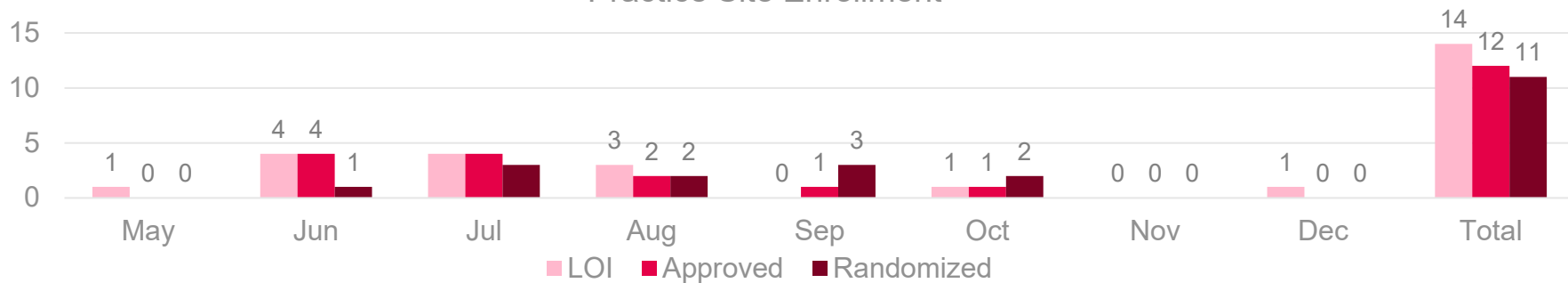
Patient History form (Spanish) – updated 12/5/24

Interview Questions (Spanish) – updated 12/5/24

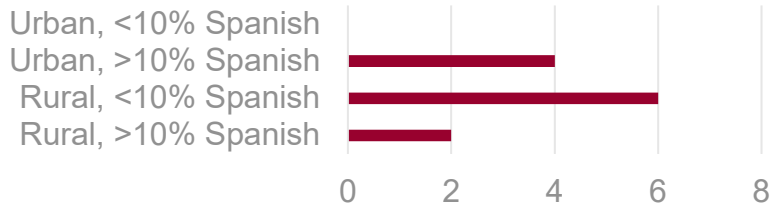
FAQs document – pending

# Progress

## Practice Site Enrollment



## Site Characteristics



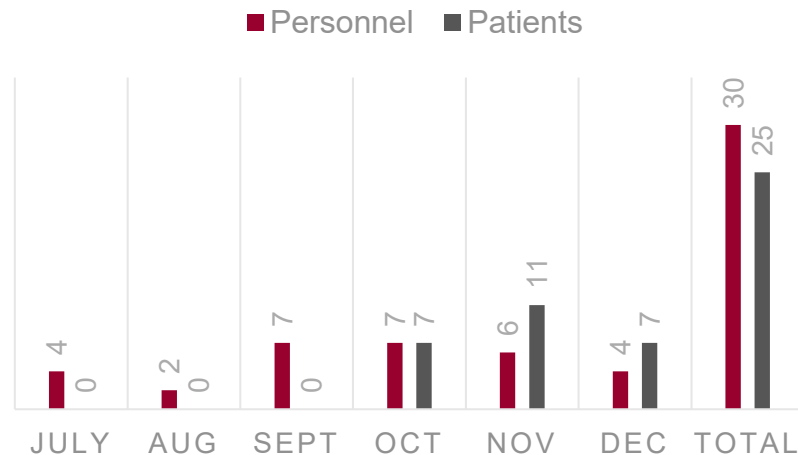
## Approved Sites



# Progress

- Opened to patient accrual 10/4/2024
- 6 sites with enrolled participants
  - Ozarks NCORP/Central Care CC
  - Upstate Carolina NCORP/Anmed
  - Ozarks NCORP AF/Lake Regional HS
  - Georgia CaRes MU NCORP
  - CommonSpirit NCORP/St. Joseph's CC
  - University of New Mexico
- 9 sites with enrolled practice personnel
  - CROWN NCORP/Aspirus Regional CC
  - Carle CC
  - Ozarks NCORP/Central Care CC
  - Georgia CaRes MU NCORP
  - Ozarks NCORP AF/Lake Regional HS
  - Puerto Rico NCORP
  - CommonSpirit NCORP/St. Joseph's CC
  - New Mexico NCORP/UNM CC
  - Stroger/Cook County MU NCORP

## ACCRUALS (12/18/24)





# Brief Study Overview



# Study Background

- There are currently more than 50 U.S. Food and Drug Administration (FDA)-approved oral anticancer agents, and their use is increasing
- Patients on oral agents must self-manage their symptoms (e.g., fatigue, anxiety, skin rash) with less interactions with on oncology team compared to infusion treatment
- Telemonitoring and management of symptoms are key for reducing symptom burden, emergency department or urgent care visits, hospitalizations, and treatment interruptions

# Study Rationale

- Testing the implementation of the following conditions in real world of community-based oncology practices:

**ATSM + TIPC**  
(Automated Telephone Symptom  
Monitoring & Handbook +/-  
Telephone Interpersonal Counseling)

**IVR Control**  
(Telephone Symptom Monitoring  
only)

- Data will inform future implementation of this telehealth symptom monitoring strategy, including acceptability, appropriateness, cost, and cost savings due to reductions in unscheduled health service use.

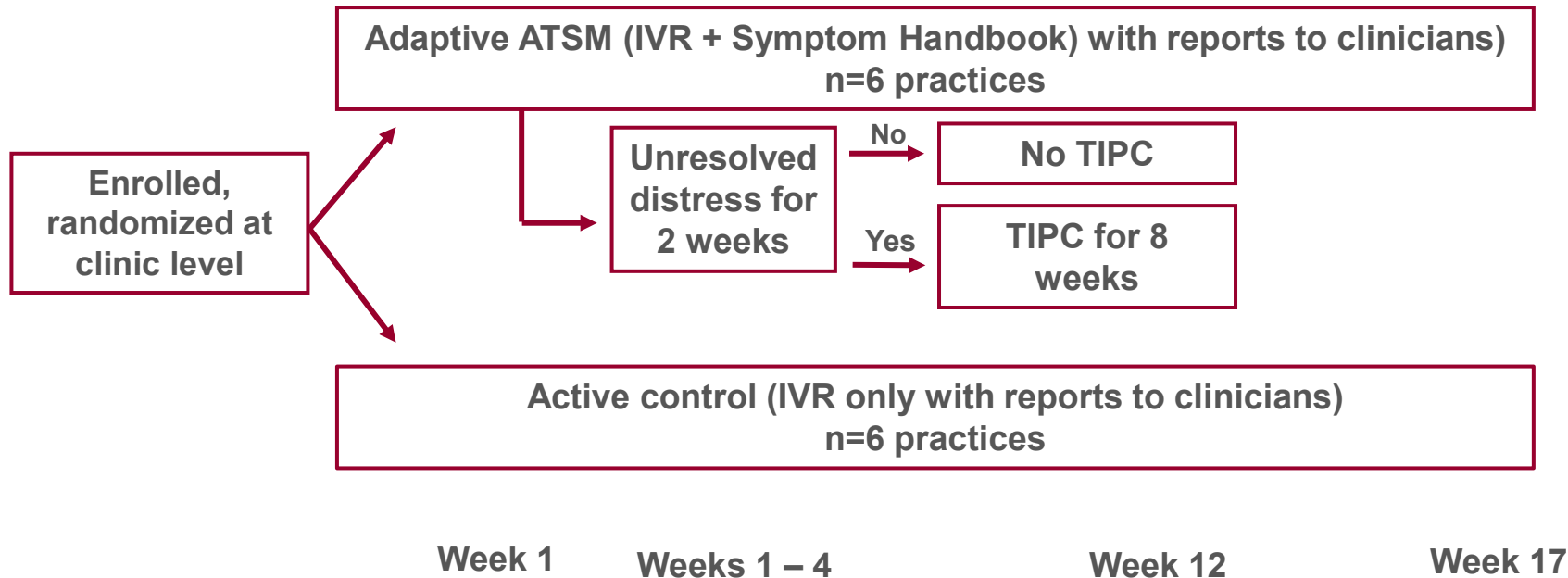
# Symptom Monitoring (both arms)

- 24 symptoms will be assessed via IVR weekly for 17 weeks using Patient-Reported Outcomes Common Terminology Criteria for Adverse Events (PRO-CTCAE)
- Symptom severity is rated as 0=none, 1=mild, 2=moderate, 3=severe, 4=very severe
- Weekly summary for each patient is sent to practice (any person or people identified by practice)
- Practice personnel are not required to do anything specific based on the report, but report recipient(s) will be asked monthly what was done

# Symptom Management (ATSM+TIPC arm only)

- Patients will be directed to a symptom management handbook in weeks 1-12, to contact their healthcare provider and/or to contact emergency services depending on their symptoms.
- Patients reported elevating psychosocial symptoms in weeks 1-4 will be referred to TIPC (telephone interpersonal counseling) for 8 weeks.

# 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

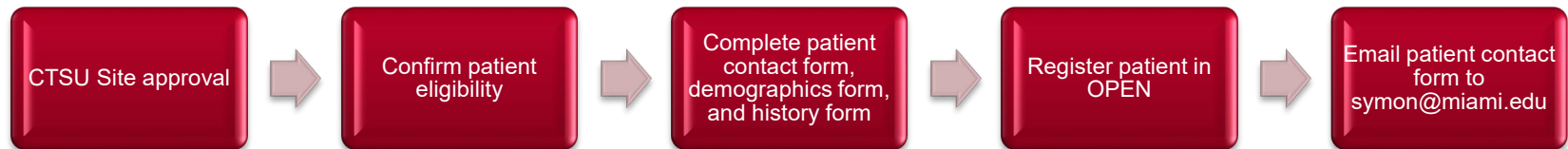
- Must be starting a new course of an oral anti-cancer agent (the list of agents is always posted to the CTSU website), within 4 weeks of registration.
  - Can be receiving sex hormone inhibitor in *conjunction* with other oral anti-cancer agent
  - **Cannot** be receiving treatment with immune checkpoint inhibitor at enrollment
  - 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)

# Patient Contact Form



- Please include time zone
- Submit within 24hours of registration in OPEN
- Email with encryption to [symon@miami.edu](mailto:symon@miami.edu)
  - If encryption not an option, contact [symon@miami.edu](mailto:symon@miami.edu) for alternative method

## NRG-CC012CD “SYMON” 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) \_\_\_\_\_

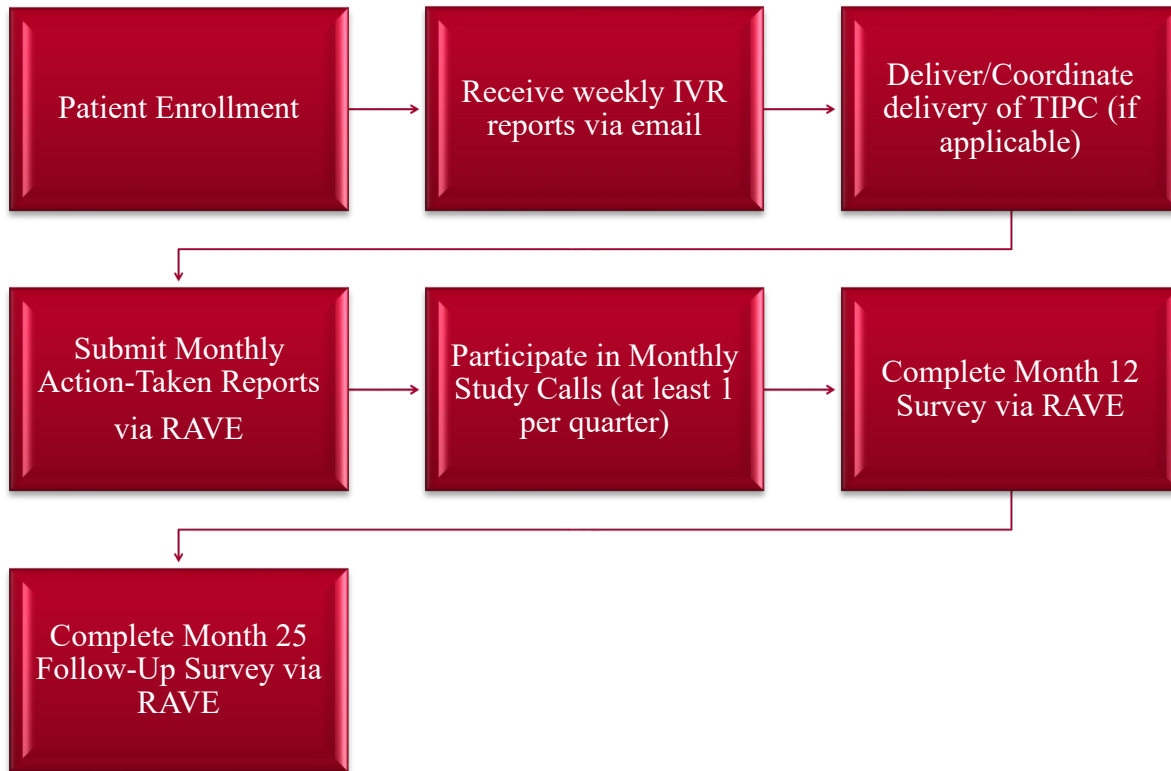
Preferred Days and Times for IVR Calls:

Day of the week \_\_\_\_\_ Time (local, include time zone) \_\_\_\_\_

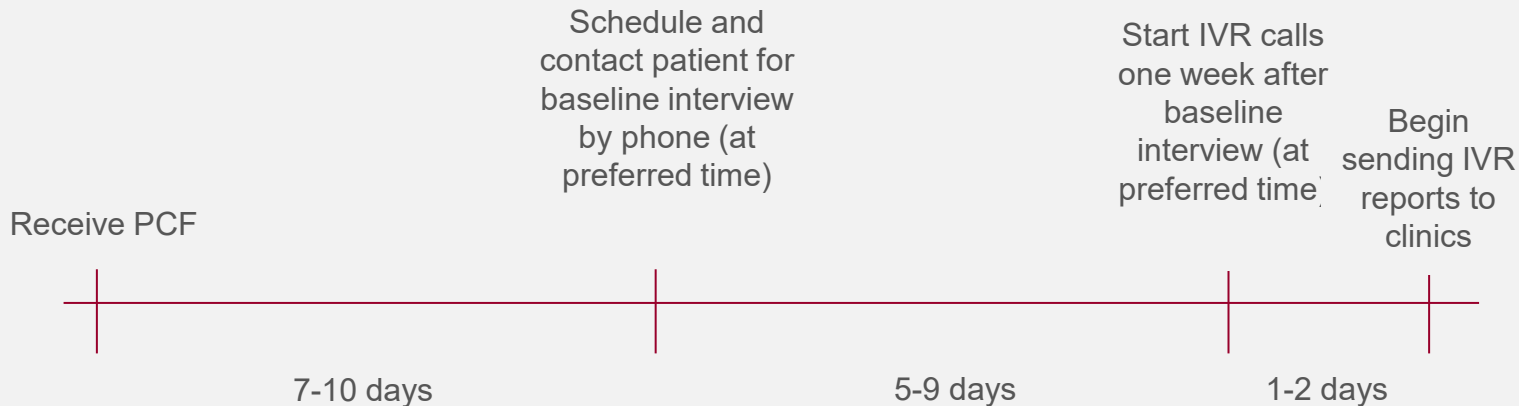
Instructions:

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)

# Practice Personnel Activities



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



# Example Weekly IVR Report

- Will be sent within ~24hrs of symptom monitoring telephone call, after each weekly call
- Can be sent to as many people as preferred

## Provider Report

Patient Name: Elle Example  
MRN: 1234567  
Study Start Date: 06/28/2024  
Below is a summary of your patient's symptoms reported on 06/29/2024

### Severe Symptoms

Cough: 4  
Arm or leg swelling: 3  
Pain: 4  
Vomiting: 4

### Moderate Symptoms

Pounding or racing heartbeat (Palpitations): 2  
Hand-foot syndrome: 2  
Headache: 1

### No Symptoms Reported

Shortness of breath: 0  
Tingling in Hands or Feet: 0  
Dizziness: 0  
Problems with concentration: 0  
Insomnia: 0  
Fatigue: 0  
Anxiety: 0  
Feeling that nothing could cheer you up: 0  
Sad or unhappy feelings: 0  
Shivering or shaking chills: 0  
Unexpected or excessive sweating: 0  
Dry mouth: 0  
Mouth or throat sores: 0  
Decreased appetite: 0  
Nausea: 0  
Constipation: 0  
Diarrhea: 9 (Refused to answer)

# Data Management

CTSU

Practice IRB approval

Protocol-specific  
training

Site registration  
documents

OPEN

Practice Enrollment

Practice Personnel  
Enrollment

Patient Enrollment

RAVE

Practice Personnel  
Demographics  
Questionnaire

Patient Screening Data

Monthly “Action  
Taken” Reports

Patient health record  
review

Feasibility and  
Acceptability  
questionnaires (months  
12 and 25 only)

[SYMION@miami.edu](mailto:SYMION@miami.edu)

LOI (retrieve from CTSU)

Patient Contact Form  
(within 1 business day  
– use encryption)

Blank Rave forms and Summary of Data  
Submission are available on the CTSU website.

# 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)







Questions?

MICHIGAN STATE  
UNIVERSITY



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