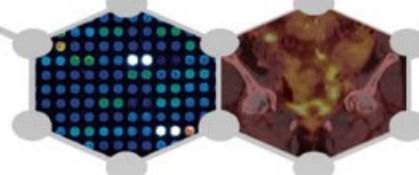

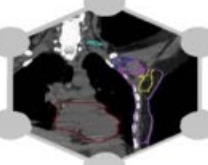

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NRG-CC012CD "SYMON"

Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment

November 21, 2024

Practice Personnel Update

Presenters:

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).

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Study Team

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

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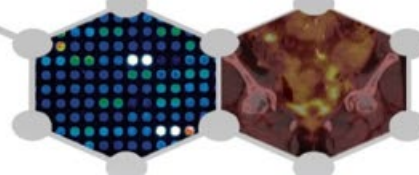

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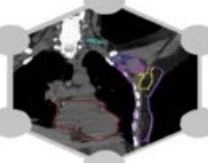

Study Updates

Protocol Amendment

Amendment 1 – 10/31/2024

- Posted to CTSU 11/18
- Only change was to list each of the recruiting sites
- ICF updated to reflect the new protocol version, but no other changes to ICFs were made

Additional approved materials like recruitment script, patient brochure in Spanish are uploaded to the CIRB documents section.

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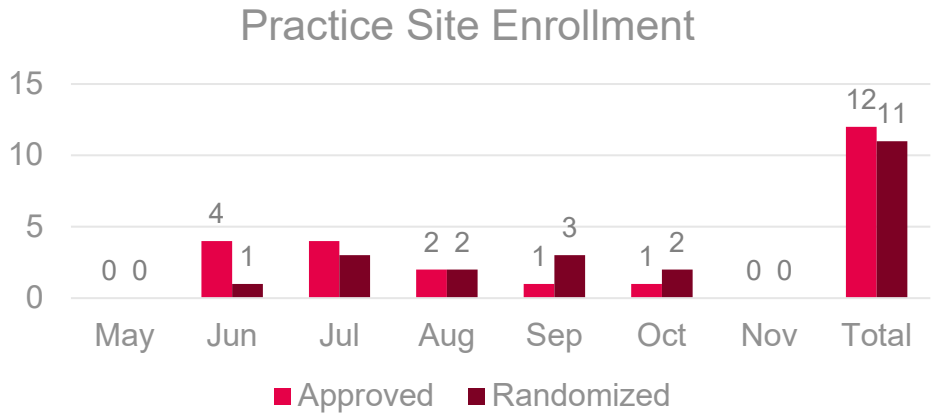
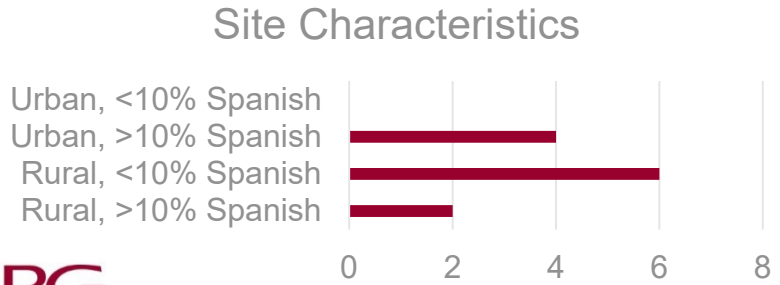
Progress





Approved Sites

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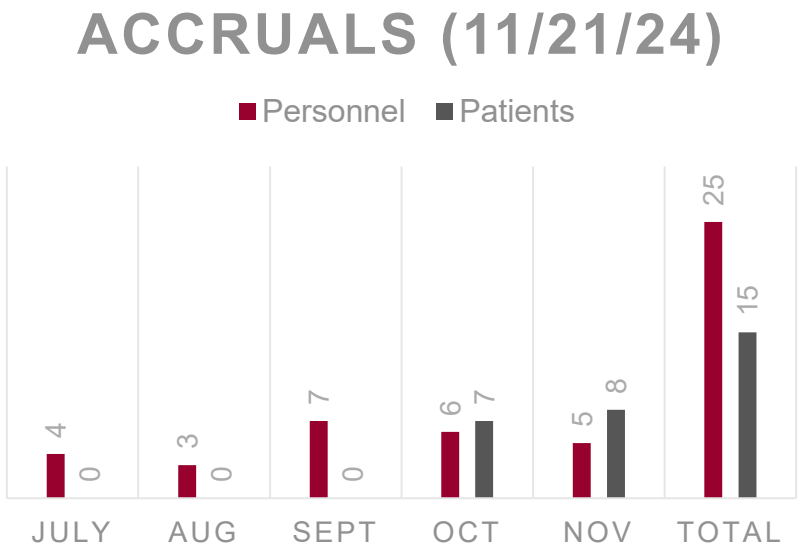
Progress

- Opened to patient accrual 10/4/2024
- 5 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
- 8 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



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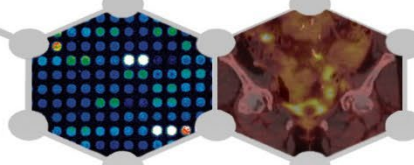

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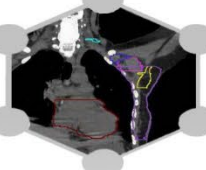

Brief Study Overview

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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

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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.

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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

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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.

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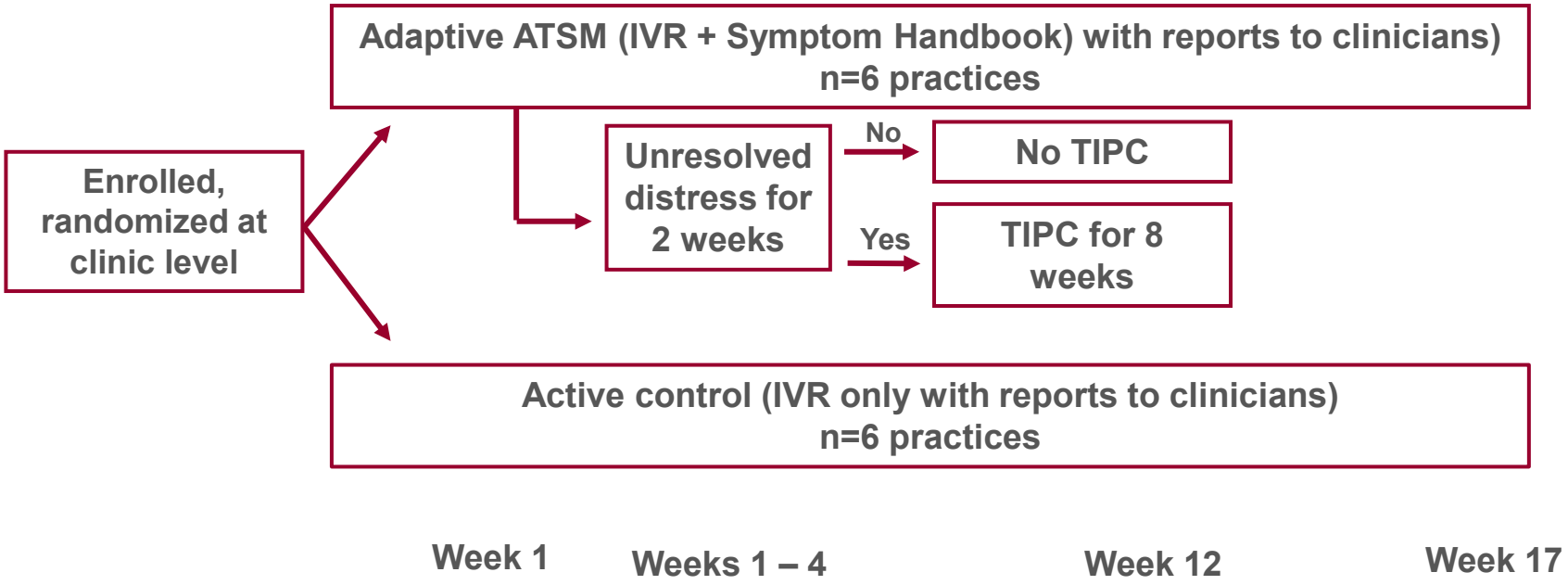
Participant Intervention



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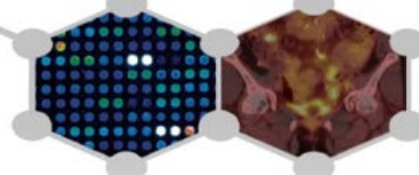
IVR = Interactive Voice Response
ATSM = Automated Telephone System Management
TIPC = Telephone Interpersonal Counseling



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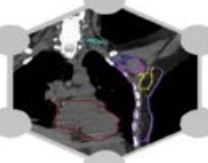

Review of Practice Study Activities

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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)

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.

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

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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

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Patient Enrollment

Plan to enroll 2 patients per month on average

Process:

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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)

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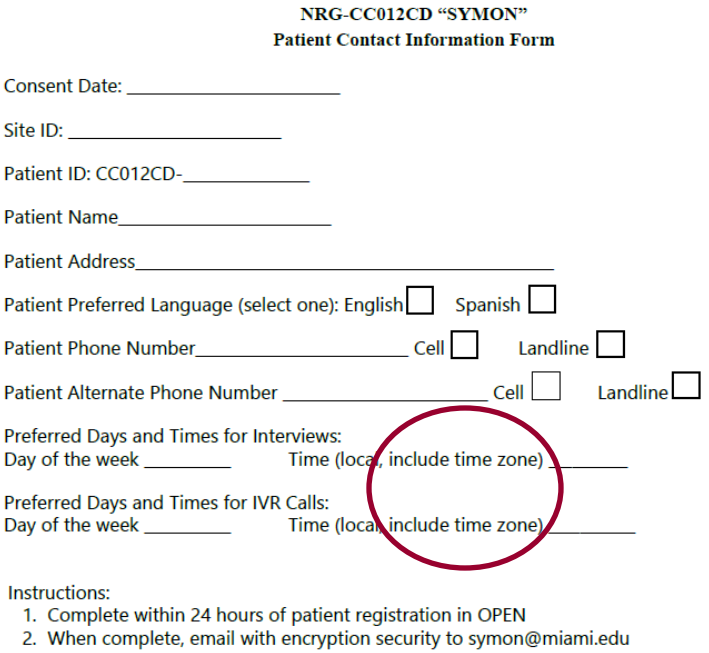
Patient Contact Form

- Please include time zone
- Submit within 24hours of registration in OPEN
- Email with encryption to symon@miami.edu
  - If encryption not an option, contact 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

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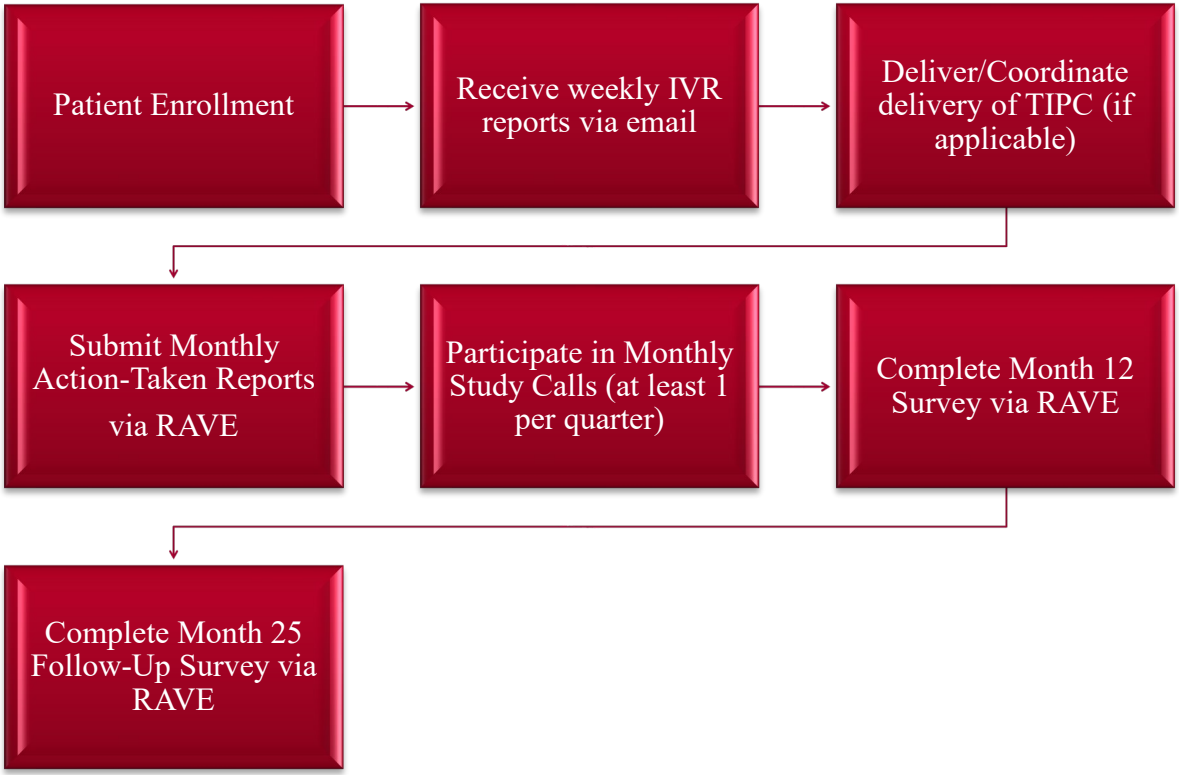
Practice Personnel Activities



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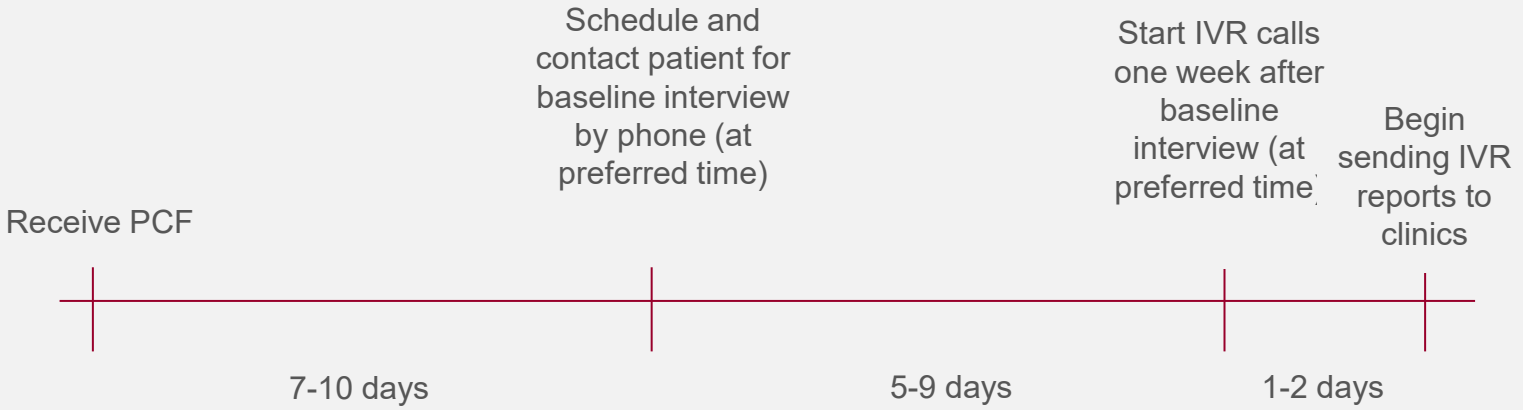
What happens between patient enrollment and beginning to receive IVR reports each week for your patients?



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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

Record ID CC012CD-00001

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)

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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)

SYMON@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.

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FAQs

Q: Should patient be starting their first ever oral anti-cancer treatment OR are medication changes to new anti-cancer medications allowed, i.e., patient switching from ibrutinib after 24 months to Zanubrutinib, etc.?
A: They can be eligible if they are starting any new course of oral agent, including changing from medication from one oral agent to another.

Q: Is a patient with some hearing impairment eligible for this study, if they have someone at home who could help by repeating the questions.
A: Yes, so long as the patient is able to answer the questions themselves.

Q: What sites should be registered in OPEN?
A: Please only register the lead site. The additional sites are included under the umbrella of the lead site. Each practice personnel participating in the study should only be enrolled once. They will also fall under the lead site even if they are seeing patients at the sister sites listed on the LOI.

Q: What should sites enter for the date of "Baseline Interview" when enrolling patients, since the site isn't responsible for completing this? When attempting to input the baseline interview date, we receive a message saying that "CBD must be greater than or equal to today's date and less than or equal to today + 10 days."
A: Please enter a calendar base date around 10 days from the date of enrollment.

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FAQs

Q: A participant reported to me that the time they are receiving automated calls (the contact time preference that they put on their form) is no longer a suitable time. How would you prefer site staff change that time?
A: Email symon@miami.edu with their new preferred time and participant ID, and we will confirm with you and change the preferred time in our system.

Q: How do we determine if a patient is eligible based off the start date for treatment and when we will consent. Are there an exact number of days we should go by or just approximately 4 weeks?
A: Four weeks is determined as exactly 4 calendar weeks. For example, if the participant started treatment on 10/8, they will be deemed ineligible and blocked from registering in OPEN after 11/5**.**

Q: A patient started an eligible oral treatment, but treatment was held for 4 weeks due to AEs. They plan to restart the oral treatment next week if the AEs are resolved. Would this be considered starting a new course of an oral anti-cancer agent?
A: No, In the situation with this patient, they are re-starting the course that began more than 4 weeks ago. Hypothetically (in case this comes up in the future), if a patient started the oral agent, but then it was paused, patient is still eligible within 4 weeks of the start even if there is temporary stoppage. As long as the decision was not to stop the agent permanently but wait and see.

*More FAQs will be published in CTSU once fully approved by NRG.

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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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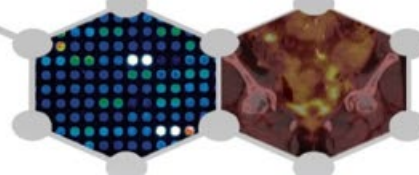

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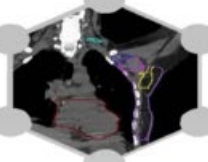

Questions?

UNIVERSITY OF MIAMI

MICHIGAN STATE UNIVERSITY

THE UNIVERSITY OF ARIZONA