NRG ONCOLOGY

Advancing Research. Improving Lives.™

NRG-CC012CD "SYMON"

Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment

18 September 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).

NRG ONCOLOGY™

NCI National Clinical Trials Network — a National Cancer Institute program

NCI Community Oncology Research Program — A program of the National Cancer Institute of the National Institutes of Health

Study Team

SYMON
SYmptom Management during Oral aNti-cancer treatment

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	

NRG ONCOLOGY™

See protocol for complete contact details

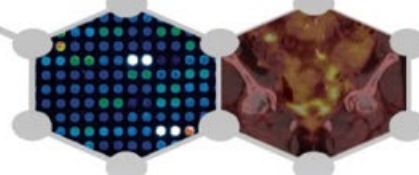
SYMON
SYmptom Management during Oral aNti-cancer treatment

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

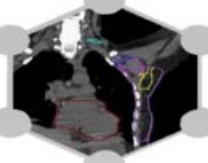
NRG ONCOLOGY™

See protocol for complete contact details



NRG ONCOLOGY

Advancing Research. Improving Lives.™

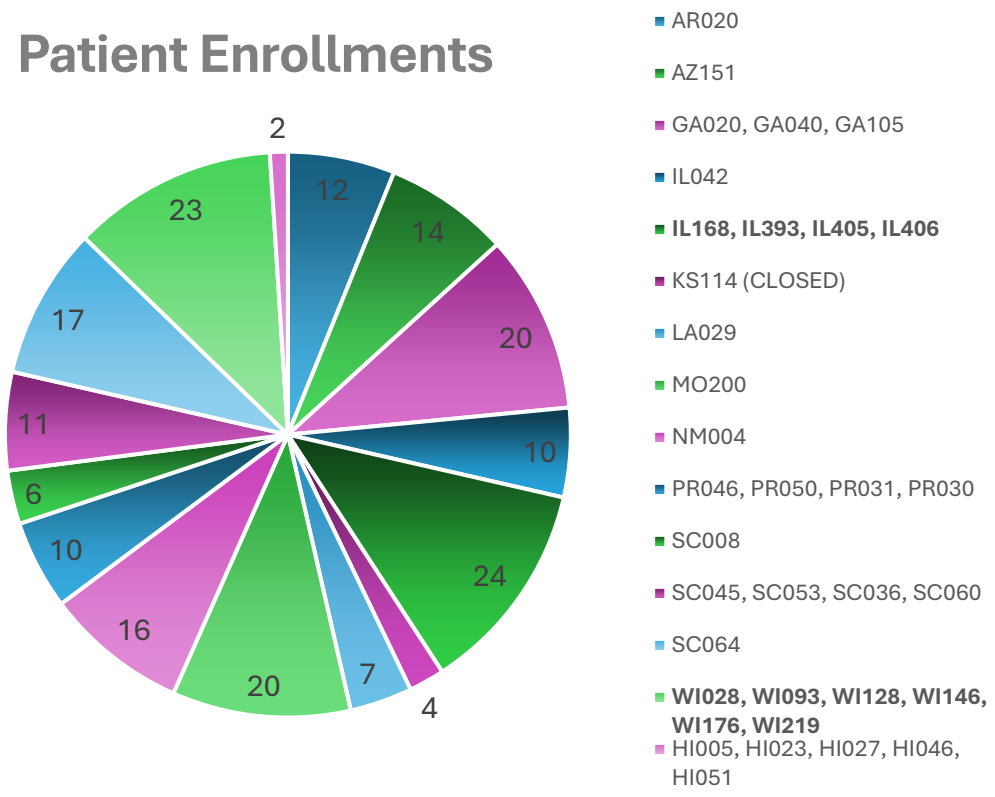


Study Updates

SYMON
SYmptom Management during Oral aNti-cancer treatment

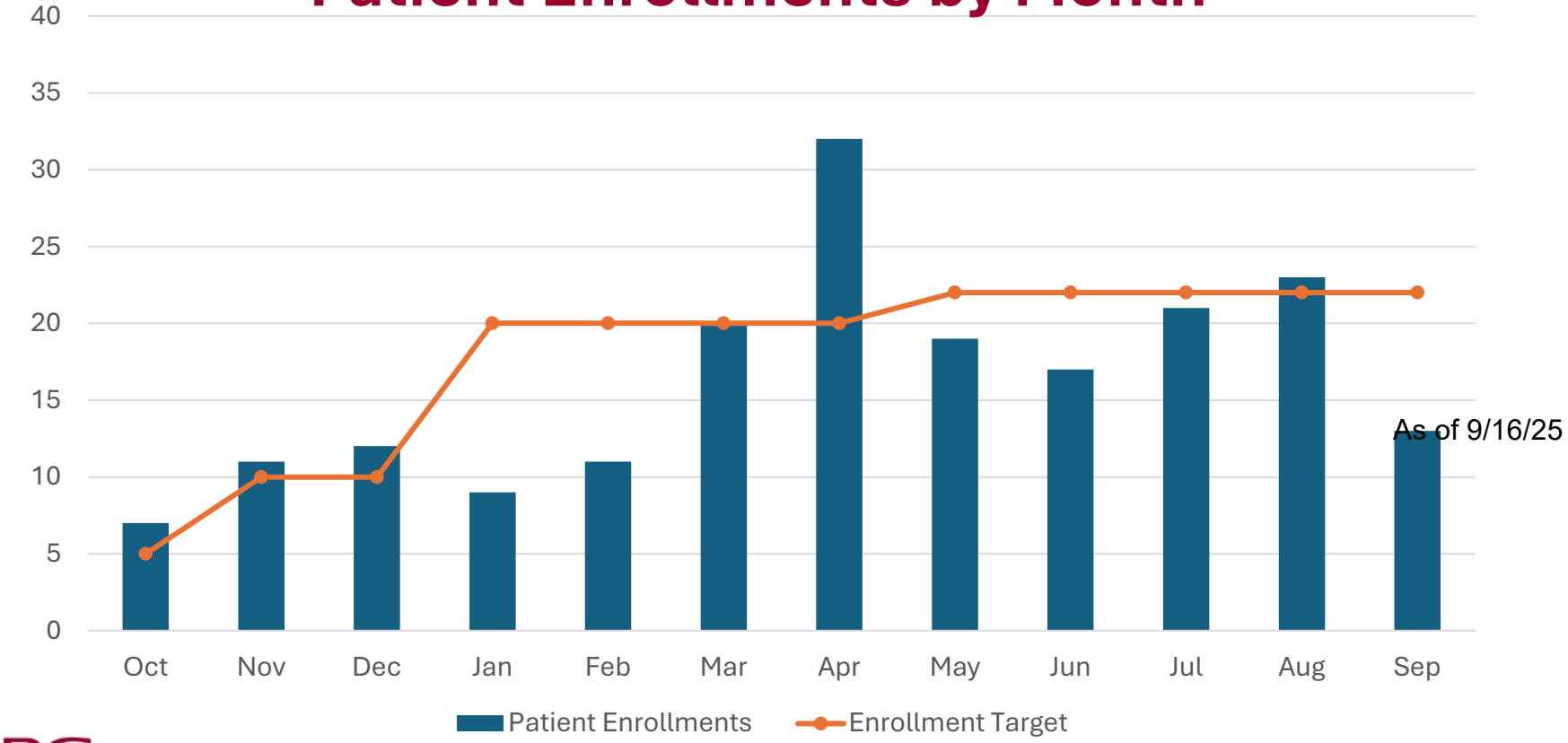
Progress

- Protocol activation 5/20/24
- Opened to patient accrual 10/4/24
  - N=196 patients enrolled (as of 9/16/2025)
  - Top enrolling sites again: Aspirus/CROWN (n=23) and Carle! (n=24)
  - Special shout out to Lake Regional Ozarks, a single site with n=20!!
- 15 sites enrolled
  - N=7 IVR “Control”, N=8 ATSM “Intervention”
  - 11 of 12 Rural-qualified practices
  - N=50 nonpatients enrolled (as of 9/16/2025)
  - Welcome officially to Hawaii, enrollment start date 8/18/25



NRG ONCOLOGY™

Patient Enrollments by Month



NRG ONCOLOGY™

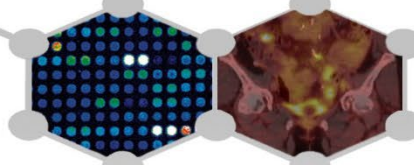
Cumulative Enrollments (past 6 mos)

Target Accrual For Period	Actual Accrual For Period	Difference	Total Accrual YTD Start 10/4/24	Goal Accrual YTD 5/20/24
4/1/25 – 4/30/25	4/1/25 – 4/30/25	(Actual - Target)	Total YTD	Goal YTD
20	32	+12	102	108
5/1/25 – 5/31/25	5/1/25 – 5/31/25	(Actual - Target)	Total YTD	Goal YTD
22	19	-3	121	120
6/1/25 – 6/30/25	6/1/25 – 6/30/25	(Actual - Target)	Total YTD	Goal YTD
22	17	-5	138	138
7/1/25 – 7/31/25	7/1/25 – 7/31/25	(Actual - Target)	Total YTD	Goal YTD
22	21	-1	160	162
8/1/25 – 8/31/25	8/1/25 – 8/31/25	(Actual - Target)	Total YTD	Goal YTD
22	23	+1	183	186
9/1/25 – 9/30/25	9/1/25 – 9/31/25	(Actual - Target)	Total YTD	Goal YTD
22	13	TBD	196	210

NRG ONCOLOGY™

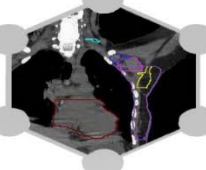
Spanish Speakers Enrollment

- Progress on 15% Spanish Speaking Goal (78/516 Total Patients)
  - 6 Practices have >10%+ Spanish Speakers (SS)
    - One site, Puerto Rico, has 99%.
  - 9 Practices have <10% Spanish Speakers
  - YTD Total Spanish Speaking Enrollments: **27**
  - YTD SS% of Total Enrollment: **13.7%**



NRG ONCOLOGY

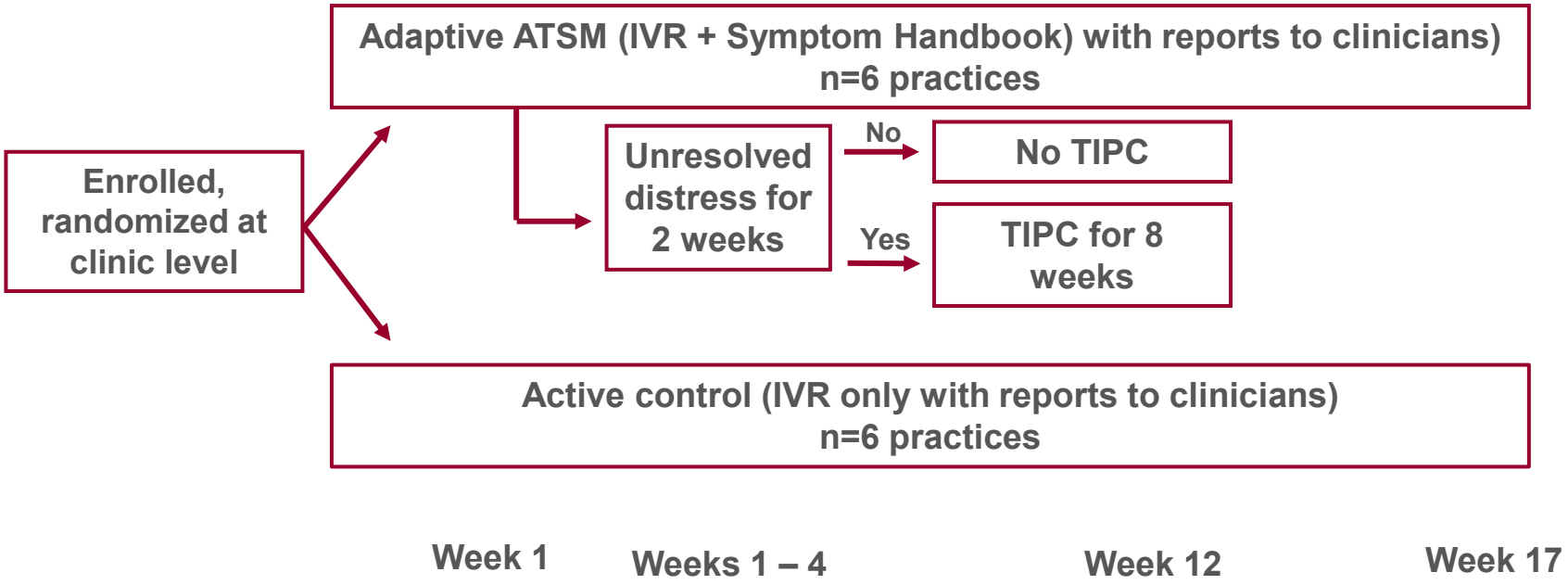
Advancing Research. Improving Lives.™



Brief Study Overview

SYMON
SYmptom Management during Oral aNti-cancer treatment

Participant Intervention



NRG ONCOLOGY™

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

Review of Practice Study Activities

SYMON
SYmptom Management during Oral aNti-cancer treatment

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

NRG ONCOLOGY™

SYMON
SYmptom Management during Oral aNti-cancer treatment

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

NRG ONCOLOGY™

Recruitment – Tips and Best Practices

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

- Update posted this week 6/23/2025

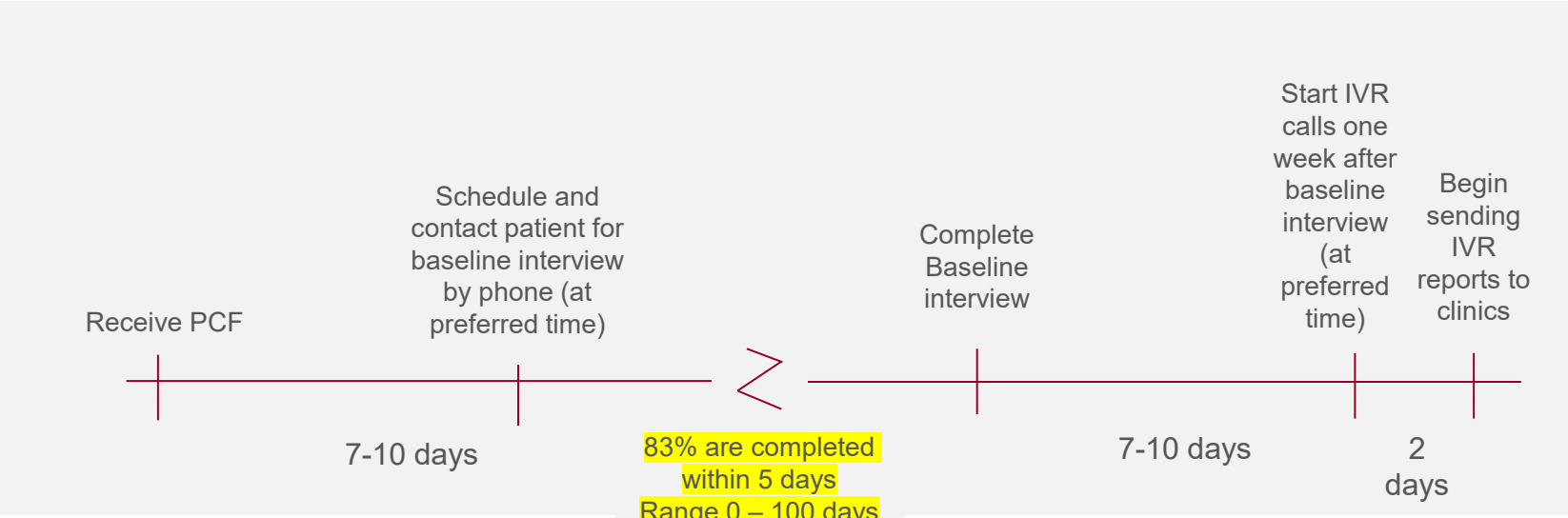
Notes

- 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.

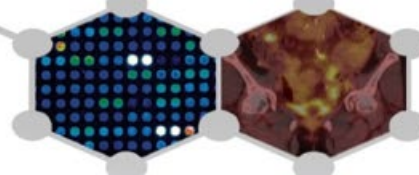
NRG ONCOLOGY™

SYMON
SYmptom Management during Oral aNti-cancer treatment

Timeline

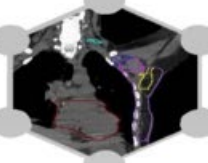


NRG ONCOLOGY™



NRG ONCOLOGY

Advancing Research. Improving Lives.™



Reminders and Questions

Reminder

To Retain Practice Participation

- **3.5.1** In order to maintain participation in the study, practices must enroll at least 8 patients in the first 6 months (based upon the practice's monthly tracking reports specified in Section 5.1) the practice is open to patient accrual to ensure that the practice can meet the accrual goals. If a practice does not meet this criterion they will be replaced. See Section 12.4.2 for detailed information on practice discontinuation.
- **3.5.2** Complete monthly forms on actions taken on IVR symptom reports. If fewer than 2 forms are completed in the first 6 months of practice's participation, practice will be replaced.
- **3.5.3** Participate in monthly study calls for the duration of practice's participation in the study.

NRG ONCOLOGY™

Recent FAQs

NRG-CC012CD FAQs are posted on CTSU (v.4.15.2025)

NRG ONCOLOGY™

Similar/Competing Studies

- **EAQ221CD CONCURxP** (Medication Adherence): Sites with this trial open should offer the CONCURxP protocol first, and then SYMON can be offered to participants who decline the first.
- **EQA222CD CostCOM** (Financial Navigation): Co-enrollment is allowed, because it is not a symptom-specific intervention
- **COSMIC WF2304-A172401** (Cannabis Cohort): Co-enrollment is allowed, because COSMIC is observational.
- **NRG-CC015**: Not competing. Breast cancer patients on this protocol must be 6 months post-treatment completion, so would not be eligible for SYMON.

NRG ONCOLOGY™

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.

NRG ONCOLOGY™

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

NRG ONCOLOGY™

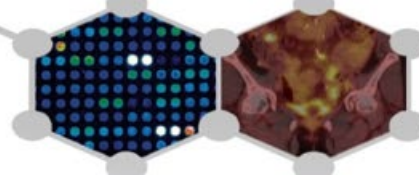
Learn More

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

  SYMON@miami.edu

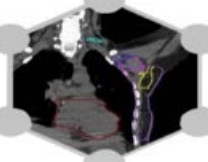
- **Resources**
  - General information:
    - www.craneresearchlab.org/cc012cd
      - Monthly Update slides will be posted here after each monthly meeting
      - Sample recording of symptom monitoring call uploaded now
    - www.nrgoncology.org/Clinical-Trials/Protocol/nrg--cc012cd?filter=nrg--cc012cd
  - NRG Meeting Kick-Off Training
    - nrg2024winter.s3.amazonaws.com/RG-CC012CD+Workshop.mp4

NRG ONCOLOGY™



NRG ONCOLOGY

Advancing Research. Improving Lives.™



Questions?

UNIVERSITY OF MIAMI

MICHIGAN STATE UNIVERSITY

THE UNIVERSITY OF ARIZONA