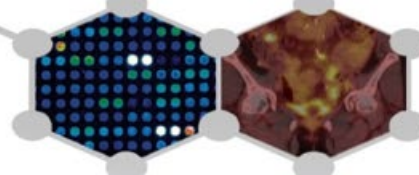

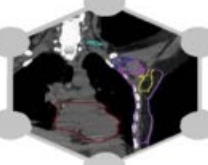

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NRG-CC012CD "SYMON"

Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment

February 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).

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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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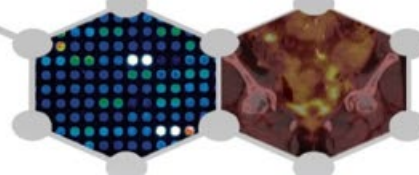
See protocol for complete contact details



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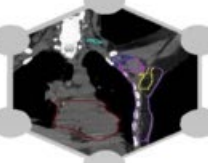

Study Updates

Protocol Amendment

No amendments since October 2024.

New amendment *in progress* to add replacement clinic site, minor changes to inclusion/exclusion criteria and forms

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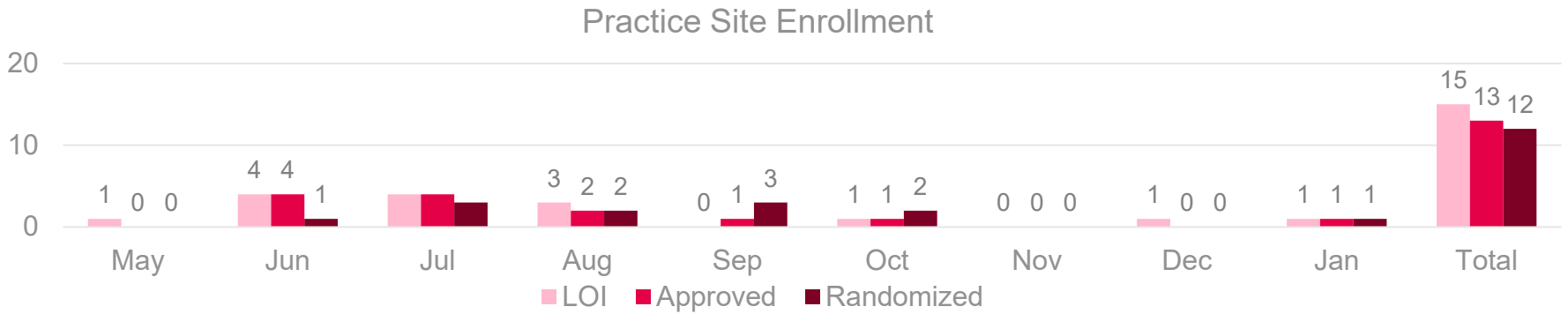
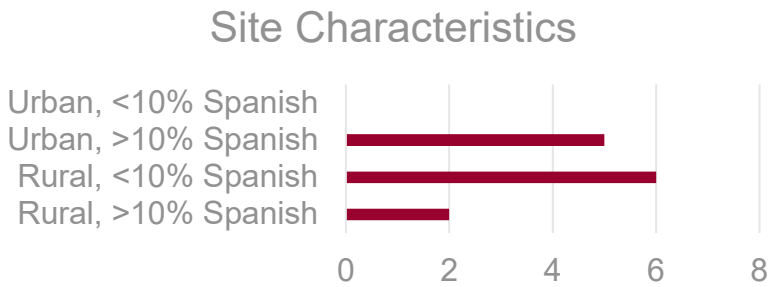
Progress





Approved Sites

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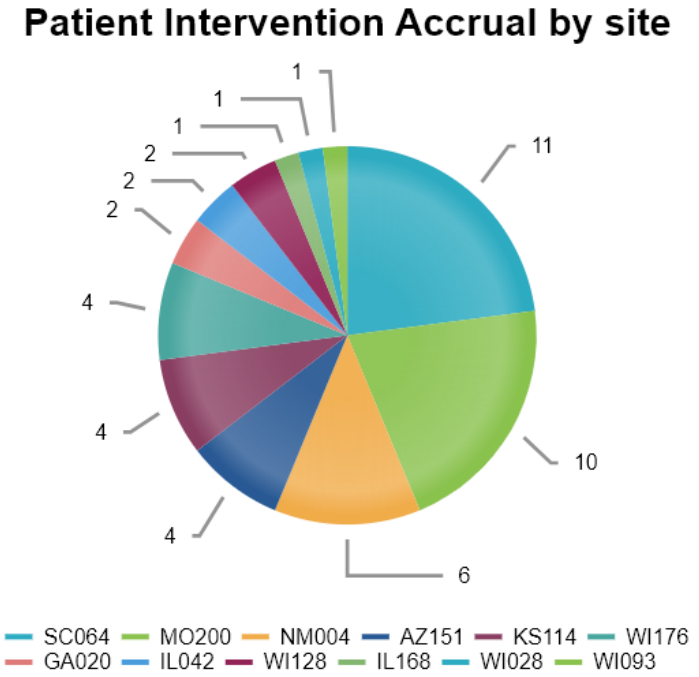
Progress

- Opened to patient accrual 10/4/2024
  - 48 patients enrolled
- 11 of 12 sites with enrolled practice personnel
  - 35 personnel enrolled



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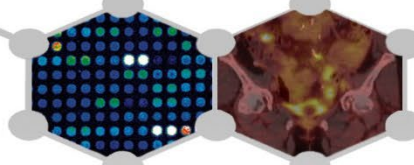

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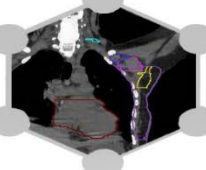

Brief Study Overview

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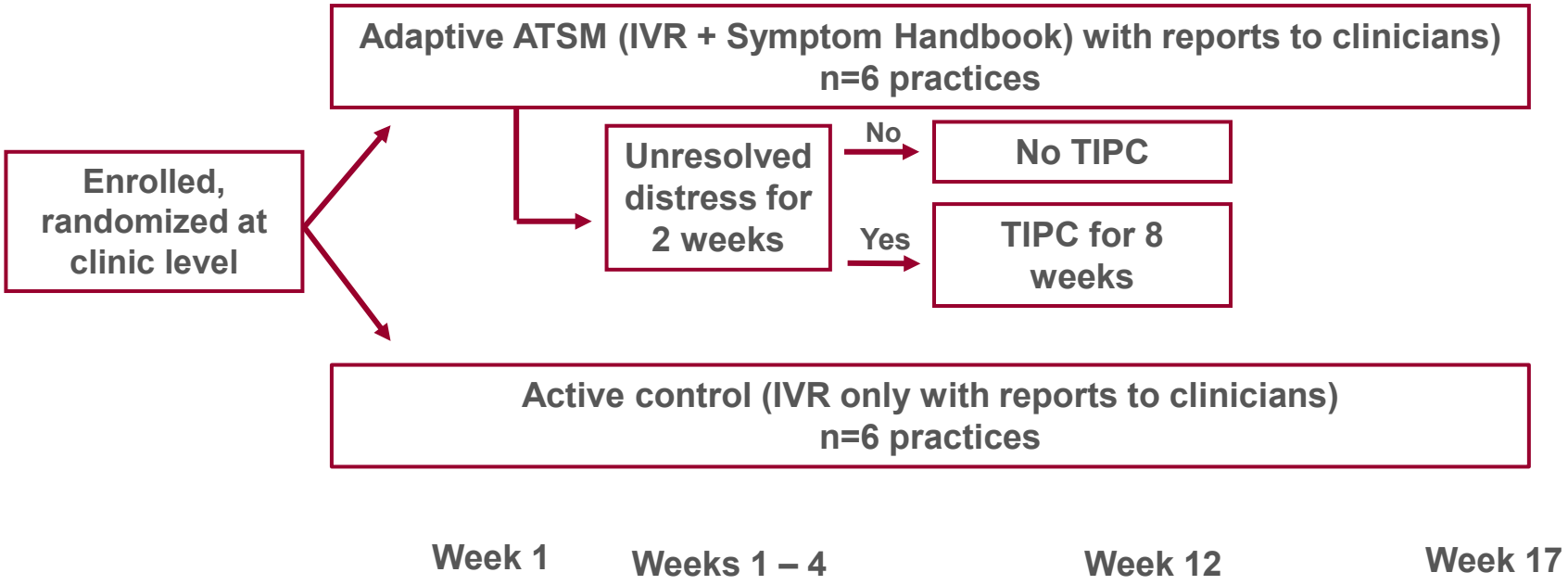
Participant Intervention



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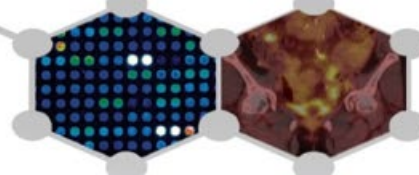
IVR = Interactive Voice Response
ATSM = Automated Telephone System Management
TIPC = Telephone Interpersonal Counseling



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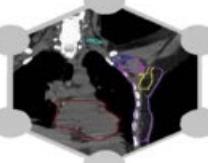

Review of Practice Study Activities

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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

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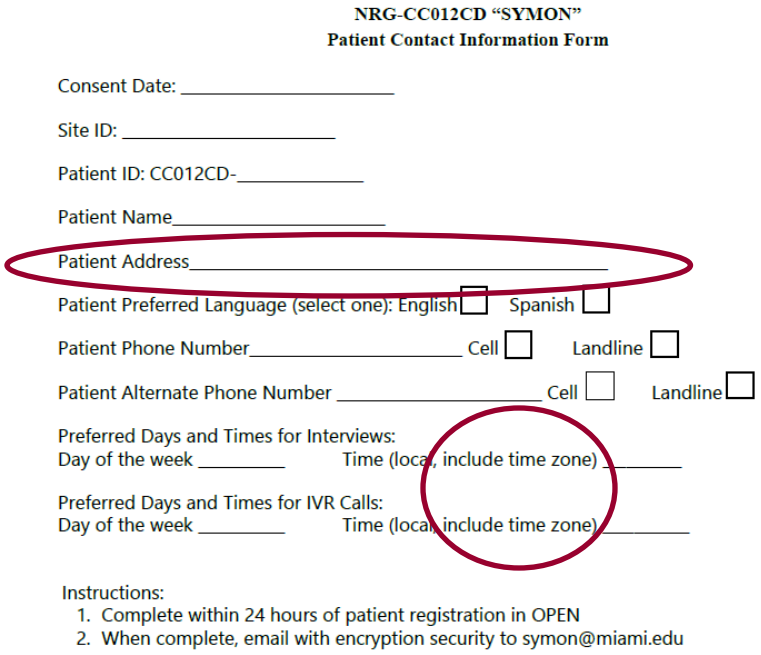
- Please include time zone
- Submit within 24hours of registration in OPEN
- Email with encryption to symon@miami.edu
  - If encryption not an option, contact symon@miami.edu for alternative method



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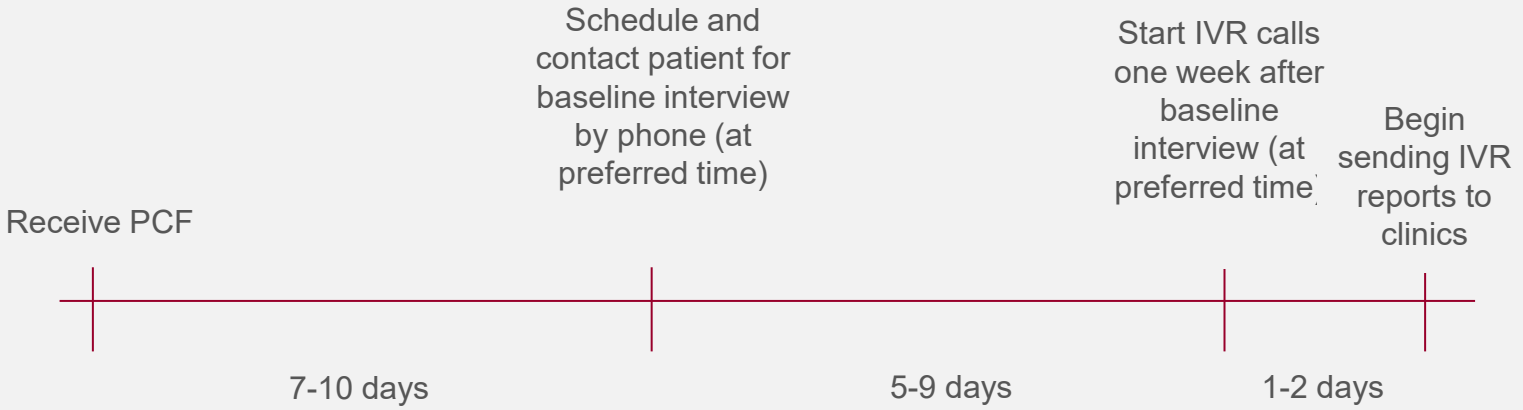
What happens between patient enrollment and beginning to receive IVR reports each week for your patients?



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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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Recent Questions/Issues

How to best manage scenarios where patients are not seen in person within 4 weeks of oral agent start

- Possible solution: Sites can add remote consenting to their CIRB study-specific worksheet
- Upcoming solution: Protocol amendment under review

Enrollment targets

- Sites can be replaced at ~6 months (IVR arm) or ~8 months (ATSM arm) if not meeting recruitment target of 2 per month, pending CIRB approval and social worker licensing if needed
- Enrollment target of 2 per month is from all sites listed on the LOI combined, not individually

Recent Questions/Issues

Clarifying protocol section 4.1 verbiage: “Baseline, 1 week prior to intervention, after the start of oral agent (may happen up 28 days after consent).”

- The 28 days after consent refers to the window of the starting the oral agent. It does not reflect the timeline for the baseline interview.

IV Targeted Therapy or Chemotherapy

- Patients receiving these concurrent with oral agent are eligible, with exception of immune checkpoint inhibitors

Recent Questions/Issues

Patients with low engagement

- We will try to reach them directly, but may reach out for support from you to confirm they want to participate and, if so, has their availability changed.
    - Your help is appreciated!
- If a patient tells you or us that they don't want to participate, they have the option to continue only interviewer assessments (week 13 and week 17) only, automated symptom calls stopped.
    - Continue to fill out Vital Status form based on last confirmed contact date.

Patients who withdraw from the study

- Submit a consent withdrawal in RAVE to stop future queries

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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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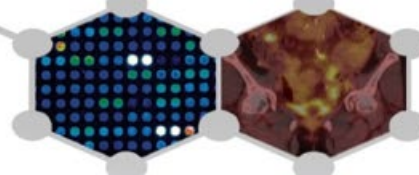

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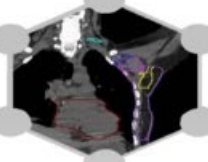

Questions?

UNIVERSITY OF MIAMI

MICHIGAN STATE UNIVERSITY

THE UNIVERSITY OF ARIZONA