



THE LOTUS CC STUDY

SCHEMA

Prior to Consent & Registration

Day 0

A1: Baseline
Day 0-Day 15

A2: Day 90
+ 15 days (Day 90-105)

A3: Day 365
+ 60 days (Day 365-425)

- Screen patients with advanced, unresectable lung, pancreatic, or colorectal cancer*
- Recently started or about to start 1st line anti-cancer therapy.**
- No planned major surgery

Consent & Register

- Chart Review
- PROs
- Physical Function Testing
- Actigraphy
- Blood Draw
- Collect Archived Tumor Sample
- Upload Imaging Scan***

- Chart Review
- PROs
- Physical Function Testing
- Actigraphy
- Blood Draw
- Upload Imaging Scan***

- Chart Review
- Upload Imaging Scan***

Abbreviations. PROs- Patient-reported Outcomes

*Patients do not need to have cachexia to be eligible.

**Patients who received systemic anti-cancer therapy previously as part of adjuvant/neoadjuvant treatment and have recurred are eligible if such treatment ended >6 months prior to enrollment. Patients receiving first-line concurrent radiation with systemic therapy or received local therapy alone (Surgery, RT) prior to first line therapy remain eligible. Patients receiving maintenance treatment after first line therapy are not eligible.

***Study uses standard-of-care scans. Extra time allocated for imaging upload during A1 and A2; Wider A3 window allows ample time for imaging upload.

4.0 PARTICIPANT ELIGIBILITY

4.1 Inclusion Criteria

Patients **must**:

4.1.1. Have a primary diagnosis of unresectable or Stage IV 1) non-small cell lung cancer (NSCLC), 2) pancreatic adenocarcinoma, or 3) colorectal cancer.

Note: Patients do not need to have cachexia to be eligible.

4.1.2. Plan to start first line systemic anti-cancer therapy (chemotherapy, immunotherapy, targeted therapy, interventional clinical trial) in the next 6 weeks or has started first-line systemic therapy in the previous 6 weeks.

NOTE: Patients who received systemic anti-cancer therapy previously as part of adjuvant or neoadjuvant treatment and have since recurred are still eligible if such treatment ended >6 months prior to enrollment. Patients receiving concurrent radiation with systemic therapy or received local therapy alone (Surgery, RT) prior to first line therapy remain eligible. Patients receiving maintenance treatment after first line therapy are not eligible.

4.1.3 Have an ECOG performance status of 0, 1 or 2.

4.1.4 Be able to understand, speak and read English.

4.1.5. Be 18 years of age or older.

4.2 Exclusion Criteria

Patients **must not**:

4.2.1 Have contraindications to physical function assessments (30-second arm curl, Timed-Up-And-Go test, or 30-second chair-stand test) per the treating provider or their designee.

4.2.2 Have any planned major surgeries within the next 3 months.

4.2.3 Have received chemotherapy or surgery for separate primary cancer within the past 3 years other than early local staged non-melanoma skin cancer.

4.2.4 Be pregnant.