

*Patient-Defined Treatment Success & Preferences in Stage IV Lung Cancer Patients***Baseline Information**

(collected at Baseline (Interview #1 or #1-A or first interview): Q1-32 & Co-Morbidity Scale on page 6)

Tracking Information

(collected at Baseline & at Interviews #2 &/or #3 & at Close)

Directions. Coordinator to complete as much as possible from medical record and/or knowledge of health care providers; may then ask patient to fill in the gaps. Questions with red numbers will most likely need to be asked of patients. Green boxes indicate required information to be submitted with informed consent.

PATIENT PARTICIPANT ELIGIBILITY CRITERIA		
1. diagnosed stage IV non-small cell lung cancer (NSCLC)	<input type="checkbox"/> 1. Yes	<input type="checkbox"/> 2. No (Exclude from study)
2. age 19 years or older	<input type="checkbox"/> 1. Yes	<input type="checkbox"/> 2. No (Exclude from study)
3. able to understand spoken English	<input type="checkbox"/> 1. Yes	<input type="checkbox"/> 2. No (Exclude from study)
4. willing and able to provide informed consent Date informed consent was signed _____	<input type="checkbox"/> 1. Yes	<input type="checkbox"/> 2. No (Exclude from study)
5. eligible to undergo chemotherapy for stage IV NSCLC, to include, but not limited to, those who: decline chemo; have not yet started chemo; are currently undergoing chemo; have completed chemo or progressed to maintenance for stage IV NSCLC within the last 30 days; elect to have chemo elsewhere (not at one of the study sites)	<input type="checkbox"/> 1. Yes	<input type="checkbox"/> 2. No (Exclude from study)
6. which chemo eligibility most closely fits this subject's situation (<i>choose only ONE</i>)		
a. have not yet started chemo for stage IV NSCLC (Interviews #1, #2, & #3)	<input type="checkbox"/>	Comment(s) _____
b. are currently undergoing 1 st line chemo for stage IV NSCLC (Interviews #2 and #3, as appropriate)	<input type="checkbox"/>	Comment(s) _____
c. have completed 1 st line chemo tx or progressed to maintenance for stage IV NSCLC within the last 30 days (Interview #3)	<input type="checkbox"/>	Comment(s) _____
d. elect to have chemo elsewhere – not at one of our study sites (Interview #1)	<input type="checkbox"/>	Comment(s) _____
e. decline chemo (Interview #1-A)	<input type="checkbox"/>	Comment(s) _____
f. other (if none of "a" through "e" above apply, obtain prior approval from Project Coordinating Center that subject is eligible and indicate reason in comment(s) section)	<input type="checkbox"/>	Comment(s) _____ _____

A. Cancer Center _____

B. Patient's Doctor _____

C. Person Entering Data _____

1. PCORI Patient # _____

2. Medical Record # (N/A in REDCap & de-identify on closing documents PRN)* _____

3. Name (N/A in REDCap & de-identify on closing documents PRN)* _____

4. Address (N/A in REDCap & de-identify on closing documents PRN)* _____

Number & Street, Apt #

(N/A in REDCap & de-identify on closing documents PRN, except ZIP required)* _____

City State Zip

5. Contact #s () () () ()
 Area Code Home Phone Area Code Work Phone
 () ()
 Area Code Mobile Phone E-mail address (optional)

6. Birthdate (month/day/year) / /

7. Gender 1. Female 2. Male

8. Height _____ feet _____ inches

9. Weight _____ pounds

10. Race (please mark ONE best answer)
 ___ Alaska Native | ___ Native
 ___ Hawaiian / Other Pacific Islander
 ___ American Indian | ___ White / Caucasian
 ___ Asian | ___ More than One Race
 ___ Black / African American
 ___ Other (please specify): _____

AGE GROUP (pick one, if these groupings are not shown in REDCap, put the age group in the comments section of the form):
 ___ a. 19-29 years ___ e. 60-69
 ___ b. 30-39 ___ f. 70-79
 ___ c. 40-49 ___ g. 80+
 ___ d. 50-59

11. Ethnicity (please mark ONE best answer)
 ___ Hispanic / Latino
 ___ Non-Hispanic / Non-Latino

12. Country of Residence, only if NOT U.S. _____

13. PRIMARY method of payment for health care (please mark ONE best answer)
 ___ Managed Care | ___ Military Sponsored (Including CHAMPUS & TriCare)
 ___ Medicaid | ___ Military or Veterans Sponsored (Not Otherwise Specified)
 ___ Medicare | ___ Veterans Sponsored
 ___ Medicaid and Medicare | ___ No Means of Payment (No Insurance)
 ___ Private Insurance | ___ Medicare and Private Insurance
 ___ Self-Pay | ___ State Supplemental Health Insurance
 ___ Other (please specify): _____

14. Current Marital Status: (check one)
 1. Never married 2. Married 3. Single
 4. Widowed 5. Divorced 6. Separated

15. Current medications (not counting chemotherapy meds – these will be listed in answer to Q #33 and Q #34). Also, include approximately how long patient has been taking each medication:

Concurrent Medications (include prescribed, over the counter, vitamins, supplements, herbal or homeopathic, etc.)	~ How Long?

16. Cancer history:

Type of Cancer	~ Year diagnosed	Chemotherapy	Surgery	Hormone Therapy	Radiation Therapy
<input type="checkbox"/> Non-Melanoma Skin Cancer (Basal or Squamous Cell) What part of body? _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Melanoma If yes, what part of body? _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Leukemia		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Lymphoma, If yes: <input type="checkbox"/> Hodgkin's <input type="checkbox"/> Non-Hodgkin's		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Mouth or Throat (Esophageal)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Thyroid Cancer		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Colon or Rectal Cancer		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Lung Cancer		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Bladder Cancer		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Kidney Cancer		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Other Cancer Type If yes, what part of body? _____ (Cervical, Prostate, Pancreatic, Liver, Ovarian, Sarcoma, Brain, Multiple Myeloma, etc.)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

17. Any blood relatives who currently have, or have had, a cancer diagnosis of any kind of cancer?

1. Yes 2. No

18. Education (highest level of schooling you completed): (*check one*)

- a. Less than High School e. Four year college degree (e.g., BA, BS)
 b. High school/GED degree f. Graduate degree (e.g., MA, MS, MBA)
 c. Some college (no degree) g. Professional degree (e.g., MD, DDS, JD)
 d. Two year college h. Postgraduate/doctoral degree (e.g., PhD, EdD)

19. Current employment status: (*check one*)

- a. Full-time (employed 32 hours or more per week)
 b. Part-time (employed less than 32 hours per week)
 c. Homemaker
 d. On medical leave
 e. Disabled, unable to work
 f. Unemployed and/or seeking work
 g. Retired
 h. Other (*please specify*): _____

20. Tobacco use: 1. Never use(d) 2. Past user 3. Current user 4. Unknown

21. Ever lived in the same house with a smoker?

1. Yes 2. No

22. If above answer is YES: Total Years: ____

23. Ever worked in an office or other enclosed area exposed to tobacco smoke?

1. Yes 2. No

24. If above answer is YES: Total Years: _____

1. Yes 2. No

25. Typical alcohol consumption? (check one)

- a. 0 / never b. occasional / 1 drink a month or so c. 1 – 2 drinks a week c. more than 3 drinks a week

26. Is anyone other than yourself (for example, family member(s), friend or someone else) dependent on you financially?

- Yes No

27. If yes, how many?

- 1 – 3
 4 – 6
 7 or more

28. Who does your personal support system include? (Check all that apply.)

- family
 friends
 work associates
 church associates
 recreation associates
 someone/several people that I live with
 other (specify category of support, not anyone's name) _____

29. Do you expect transportation to be a treatment barrier?

- Yes
 No

30. If yes, please explain _____

31. Was your total income (before taxes) in the past 12 months \$45,000 or more? (check one)

1. Yes 2. No 3. Prefer not to report / Not reported / Unknown

32. What category best describes your total combined family income in the past 12 months (you plus your family, before taxes)? (check one)

1. \$0-14,999 3. \$30,000-44,999 5. \$60,000-74,999 7. Prefer not to report, Not reported, or Unknown
 2. \$15,000-29,999 4. \$45,000-59,999 6. \$75,000 or more

To be completed as much as possible with information from the medical record –

1. 1st Line Treatment Regimen (name of chemo drugs, dosage and frequency planned; and dates of treatments completed):

2. More 1st Line Treatment Regimen, if changes from above (give reason for change, and name of new chemo drugs, new dosage and/or frequency planned, if applicable; and give dates of treatments completed):

3. Adverse Side Effects/Events noted in medical record from date case opened (ICF signed) to date

case closed (directions: summarize/list AEs recorded in the medical record by inputting into REDCap & submitting to coordinating center at baseline (T-0), Interview #2 (T-1) & Interview #3 (T-2). Or, may copy, scan and fax AE forms from patient chart/medical record or send via REDCap Send-It – after obliterating all patient-identifiers, except the PCORI Patient ID #):

4. Date case closed:

Closing notes, including reason for closure and dates of events, if they are different than the date of closure: (e.g., completed participation, patient voluntarily withdrew from study, patient too ill to continue, moved away, declared lost to follow-up, died, or other reason(s) [if “other reason(s),” please specify reasons and give pertinent dates] _____)

5. Other comments/notes:

*Patient-Defined Treatment Success & Preferences in Stage IV Lung Cancer Patients*CIRS Co-morbidity Scale¹ Scoring Sheet

PATIENT'S Initials _____

AGE _____

RATER(S) Initials _____

DATE SCORED _____

Directions: Coordinator to complete from information found in the patient's medical record. Use rating strategy below to assign a score, one for each item "a" through "n." For scores of 3 or 4, on the line next to the item, write brief descriptions of the medical problem(s) that justify the endorsed score. No descriptions are needed for scores less than 3.

Rating Strategy:

0 = NONE: No problem

1 = MILD: Current mild problem or past significant problem

2 = MODERATE: Moderate interference with normal activity or morbidity that may require some treatment

3 = SEVERE: Constant significant impairment that requires treatment / "uncontrollable" chronic problems

4 = EXTREMELY SEVERE: Immediate treatment required / end organ failure / severe impairment in function

- a. Cardiac _____
- b. Hypertension _____
- c. Vascular (blood, blood vessels and cells, marrow, spleen, lymphatics) _____
- d. Respiratory (lungs, bronchi, trachea below the larynx) _____
- e. EENT (eye, ear, nose, throat, larynx) _____
- f. Upper GI (esophagus, stomach, duodenum, biliary and pancreatic trees; does not include diabetes) _____
- g. Lower GI (intestines, hernias) _____
- h. Hepatic (liver only) _____
- i. Renal (kidneys only) _____
- j. Other GU (ureters, bladder, urethra, prostate, genitals) _____
- k. Musculoskeletal / integumentary (muscles, bone, skin) _____
- l. Neurological (brain, spinal cord, nerves (does not include dementia) _____
- m. Endocrine / Metabolic (includes diabetes, diffuse infections, other infections, and toxicity) _____
- n. Psychiatric / Behavioral (includes depression, anxiety agitation, psychosis, does not include dementia) _____

¹Cummulative Illness Rating Scale for Geriatrics (CIRS-G), Adapted from Miller, Paradis, and Reynolds 1991