



ACRIN 6678
Registration/Eligibility Checklist
FDG-PET/CT Tumor Response
Patient Outcome - NSCLC

ACRIN Study 6678
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, please box.

Instructions: The eligibility checklist (A0) Part 2 must be completed prior to registration to determine and confirm study eligibility. At the time of enrollment, the participant is to review, sign and date the consent. The following questions will be asked at study registration. The date is submitted via the ACRIN website. Submit a paper form only in the event the website is down.

Part I. The following questions will be asked at Study Registration:

- _____ 1. Name of Institutional person registering this case [1]
- _____ 2. **(Y)** Has the Eligibility Checklist been completed? [2]
- _____ 3. **(Y)** Is the Patient eligible for this study? [3]
- _____-____-____ 4. Date the study-specific Consent Form was signed? (mm-dd-yyyy) **(Must be prior to study entry)** [4]
- _____ 5. Patient's Initials (*last, first*) (L, F) [5]
- _____ 6. Verifying Physician (Site PI) [6]
- _____ 7. Participant's ID Number (optional: 999999 may be coded) [7]
- _____-____-____ 8. Date of Birth [mm-dd-yyyy (must be = or > than 18 years)] [8]
- _____ 9. Ethnicity [9]
 - 1 Hispanic or Latino
 - 2 Not Hispanic or Latino
 - 9 Unknown
- _____ 11. Gender [11]
 - 1 Male
 - 2 Female
- _____ 12. Participant's country of residence (if other, complete Q18) [12]
 - 1 United States
 - 2 Canada
 - 3 Other
 - 9 Unknown
- _____ 13. Zip Code (5 digit code, US residents) [13]
- _____ 14. Patient's Insurance Status [14]
 - 0 Other
 - 1 Private Insurance
 - 2 Medicare
 - 3 Medicare and Private Insurance
 - 4 Medicaid
 - 5 Medicaid and Medicare
 - 6 Military or Veteran's Administration
 - 7 Self Pay
 - 8 No means of payment
 - 9 Unknown/Decline to answer
- _____ 15. Will any component of the patient's care be given at a Military or VA facility? [15]
 - 1 No
 - 2 Yes
 - 9 Unknown

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- ____ - ____ - ____ 16. Calendar Base Date [= date of registration] [16]
- ____ - ____ - ____ 17. Date of registration [randomization] (mm-dd-yyyy) [17]
- ____ 18. Other Country, specify (completed if Q12 is coded "other") [18]
- Race (check all that apply) =1 No, =2 Yes
19. American Indian or Alaskan Native [19]
20. Asian [20]
21. Black or African American [21]
22. Native Hawaiian or other Pacific Islander [22]
23. White [23]
24. Unknown [24]
- ____ - ____ - ____ 25. Start date of planned chemotherapy treatment (mm-dd-yyyy) (Group A and B only. Enter 99's for Group C) [25]

Part II: The following questions are to determine patient eligibility:

- ____ 26. (Y) Does the participant have histologically or cytologically proven NSCLC? [26]
- ____ 27. (Y) Does the participant have tumor stage IIIB (with malignant pleural effusion), stage IV, or recurrent metastatic disease? [27]
- ____ 28. (Y/NA) Has the participant had a CT or MR scan of the **chest**? [28]
NOTE: If necessary to determine/confirm stage disease, an upper abdomen CT scan (including liver and adrenals) must be performed.
- ____ - ____ - ____ 29. Please provide date of CT or MR [29]
- ____ 30. (Y) Has the participant had a history and physical examination within 6 weeks prior to registration? [30]
- ____ - ____ - ____ 31. Please provide date of physical examination. [31]
- ____ 32. (Y/NA) Has the participant had a CT or MR scan of the **brain** within 4 weeks prior to registration if there is headache, mental or physical impairment, or other signs or symptoms suggesting brain metastases... (Group A and B only) [32]
- ____ - ____ - ____ 33. Please provide date of CT or MR [33]
- ____ 34. (Y) Does the participant have at least one measurable primary or other intrathoracic/supraclavicular lesion ≥ 2 cm according to Response Evaluation Criteria in Solid Tumors (RECIST)? [34]
- ____ 35. (Y) Does the participant have a performance status of 0 to 2 on the Eastern Cooperative Oncology Group (ECOG) scale? [35]
- ____ 36. Please provide Performance Status (ECOG). [36]
- 0 Fully active, able to carry on all pre-disease performance without restriction
 - 1 Restricted in physically strenuous activity but ambulatory and able to carry out of a light or sedentary nature, e.g., light house work, office work
 - 2 Ambulatory and capable of all selfcare but unable to carry out work activities. Up and about more than 50% of waking hours
 - 3 Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
 - 4 Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
 - 5 Dead
- ____ - ____ - ____ 37. Please provide date the Performance Status (ECOG) was assessed. [37]

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- _____ 38. (Y/NA) Is the participant scheduled to be treated with a platinum-based dual-agent chemotherapy regimen administered at 3 weeks intervals? (Group A and B only) [38]
- _____ 39. (Y) Is the participant 18 years of age or older? [39]
- _____ 40. (Y/NA) Does the participant agree to use medically appropriate contraception if sexually active; women of child bearing potential must not be pregnant or breast-feeding [40]
- _____ 41. (Y/NA) Has a pregnancy test been done and shown to be negative? [41]
- _____ 42. If yes, please provide date of pregnancy test. [42]
- ___ -
- _____ 43. (Y) Is the participant able to give study specific informed consent? [43]
- _____ 44. (Y) Is the participant able to tolerate PET imaging required by protocol, to be performed at an ACRIN-qualified facility? [44]
- _____ 45. (Y) Which treatment arm is the participant being registered to? [60]
- Group A
 Group B
 Group C

Exclusion Criteria:

- _____ 46. (N) Does the participant have small cell carcinoma histology? [46]
- _____ 47. (N) Does the participant have a pure bronchioloalveolar cell carcinoma histology? [47]
- _____ 48. (N) Has the participant had prior thoracic radiotherapy, lung surgery or chemotherapy within 3 months prior to inclusion in the study? (Radiotherapy or surgery non-thoracic lesions allowed) [48]
- _____ 49. (N) Does the participant have poorly controlled diabetes (defined as fasting glucose level >150 mg/dl) despite medications? [49] (see Section 5.2.4 for details)
- _____ 50. (N) Has the participant had a prior malignancy other than basal cell or squamous cell carcinoma of the skin, carcinoma in situ, or other cancer from which they have been disease free for less than (3) years? [50]
- _____ 51. (N/NA) Is the participant planning to undergo chemoradiotherapy? (Exclusion for Group A and B only) [51]
- _____ 52. (N) Does the participant show clinical or radiographic signs of post-obstructive pneumonia? [52]
- _____ 53. (N/NA) Does the participant have symptomatic brain metastases? (Exclusion for Groups A and B only) [53]
- _____ 54. (N/NA) Treatment planned with any targeted or biologic therapy other than bevacizumab or cetuximab? (Exclusion for Groups A and B only) [59]
- _____ 55. (N) Is the participant, who is sexually active, unwilling and/or unable to use medically appropriate contraception, or women who are pregnant or breast-feeding? [55]

Completed by: _____ [56]
(Research Associate, Investigator Designee, or Principal Investigator)

_____ [57]
Signature of person entering data onto the web

Date form completed _____ - _____ - _____ (mm-dd-yyyy) [58]