

NORTH CENTRAL CANCER TREATMENT GROUP
Pre-Registration (Step 1) Eligibility Checklist

02/18/2011
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N0871: A Phase II Study of Carboplatin (CBDCA), Paclitaxel (TAXOL), and Everolimus (RAD001) in Previously Untreated Patients with Measurable Disease with Cancer of Unknown Primary (CUP)

To pre-register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application.

Pre-Registration date (date on) (mm/dd/yyyy) ___/___/___

Patient study ID number (provided at time of Pre-Registration) _____

NCCTG member (participant sponsor) _____

NCCTG treating location _____

NCCTG treating physician _____

Institution patient number (local subject number) _____

IRB approval date (mm/dd/yyyy) ___/___/___

Person Completing Form:

Last Name: **(print)** _____ First Name: **(print)** _____

Phone: _____ Fax: _____ Email: _____

Patient initials (last, first, middle) ___ ___ ___

Gender (check one) ___ Male ___ Female ___ Unknown

Date of birth (mm/dd/yyyy) ___/___/___

ZIP code _____

Country of Residence _____

Method of payment (check one)

- PI (Private Insurance)
- MR (Medicare)
- MRP (Medicare and Private Insurance)
- MD (Medicaid)
- MM (Medicaid and Medicare)
- MVA (Military or Veterans Sponsored,
Not Otherwise Specified (NOS))
- MS (Military Sponsored [including CHAMPUS & TRCARE])
- MV (Veterans Sponsored)
- SP (Self pay [no insurance])
- NP (No means of payment [no insurance])
- OTH (Other)
- UNK (Unknown)

Race (check all that apply)

- White
- Black or African American
- Native Hawaiian or Other Pacific Islander
- Asian
- American Indian or Alaska Native
- Not reported: Patient refused or not available
- Unknown: Patient unsure

Ethnicity (check one)

- Not Hispanic or Latino
- Hispanic or Latino
- Not reported: Refused or data not available
- Unknown: Unsure of their ethnicity

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Patient study ID number _____

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be *mm/dd/yyyy*.

Pre-Registration – Inclusion Criteria

Yes No NA

Submission of tissue for central review to determine if there is adequate tissue to address mandatory correlative components (see Section 17.2) OR documentation that adequate tissue is not available and that a re-biopsy has been scheduled. Note: Tissue should be submitted as soon after pre-registration as possible.	___	___	___
Willing to be re-biopsied if additional tissue is needed to satisfy Section 3.11 criteria (see Section 17.2).	___	___	___
Carcinoma of unknown primary after the following diagnostic procedures have been performed and are unrevealing of the primary site: <ul style="list-style-type: none"> • Complete history and physical • CBC, chemistries • Chest x-ray and/or CT scan • Abdominal/pelvis CT • Directed evaluation of symptomatic areas • Mammogram in women • Colonoscopy in patients with liver metastasis or an elevated CEA 	___	___	___
NOTE: If a primary carcinoma is identified, the patient should undergo treatment as appropriate for that primary tumor and not be enrolled in the study.			

All responses in above section must be “Yes”.

Pre-registration – Exclusion Criteria

Yes No NA

Prior chemotherapy for this cancer. NOTE: Bisphosphonates are allowed.	___	___	___
Prior radiation therapy to >25% bone marrow: NOTE: Prior radiation for this cancer is allowed if performed for palliative reasons.	___	___	___
Any of the following: <ul style="list-style-type: none"> ▪ Neuroendocrine tumors ▪ Women with axillary nodes only ▪ Women with adenocarcinoma of peritoneum ▪ Carcinoma involving only one site, with resectable tumor at that site ▪ Squamous carcinoma limited to cervical, supraclavicular, or inguinal lymph nodes ▪ Men with poorly differentiated mediastinal or retroperitoneal tumor with stains suggestive of germ cell origin or serum tumor markers (AFP/HCG). These tumor markers are only required if the patient fits this clinical scenario. ▪ Men with prominent blastic bony metastasis or markedly elevated PSA, suggesting prostate origin ▪ If immunostains are performed, and any of the below tests are positive: <ul style="list-style-type: none"> - Hematologic CD45+ (others such as CD2, CD20, CD30, CD43 also suggest hematologic origin) - Melanoma (S-100 or HMB45) - Chromogranin or synaptophysin - Lung or thyroid origin (Thyroid Transcription Factor [TTF-1]) 	___	___	___
NOTE: Patients with biopsy-proven TTF-1 positive tumor who do not have clinical evidence for either lung or thyroid cancer (e.g., a dominant lung mass) are still eligible.			

All responses in above section must be “No”.

Pre-Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be *mm/dd/yyyy*.

Yes No NA

Consent form signed and dated. Date informed consent signed ___/___/_____	___	___	___
Authorization for use and disclosure of protected health information (<i>U.S.A. institutions only</i>) signed and dated. If not a USA institution (<i>check NA</i>) If a USA institution - Date of authorization ___/___/_____	___	___	___
The site has reviewed and understands the process listed in Sections 17.2 and 17.3 and must account for sufficient time to complete pre-registration and registration steps.	___	___	___

All responses in above section must be “Yes” unless specified as “NA.”

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Patient study ID number _____

Assigned Treatment

_____ Pre-registration

Person pre-registering Signature _____ Registration Office specialist initials _____

Physician Signature _____ Date (mm/dd/yyyy) __ __ / __ __ / __ __ __ __