

Eligibility Checklist

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N064A: Phase II Study of Panitumumab, Chemotherapy, and External Beam Radiation in Patients with Locally Advanced Pancreatic Cancer

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

Has the patient ever been on a prior study entered through this Registration Office? Yes No

If yes: Prior study number _____; prior patient study ID number _____

Registration date (date on) (mm/dd/yyyy) ___/___/_____
Patient study ID number (provided at time of Reg/Random) _____
NCCTG member (participant sponsor) _____
NCCTG treating location (chemo) _____
(RT) _____
NCCTG treating physician (chemo) _____
(RT) _____
Institution patient number (local subject number) _____
IRB approval date (chemo) (mm/dd/yyyy) ___/___/_____ IRB approval date (RT) (mm/dd/yyyy) ___/___/_____
Person Completing Form:
Last Name: (print) _____ First Name: (print) _____
Phone: _____ Fax: _____ Email: _____

Patient initials (last, first, middle) _____ (For Mayo Rochester patients, include first four letters of last name.)	Race (check all that apply)
Gender (check one) <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	<input type="checkbox"/> White
Date of birth (mm/dd/yyyy) ___/___/_____	<input type="checkbox"/> Black or African American
Zip code _____	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander
Country of Residence _____	<input type="checkbox"/> Asian
	<input type="checkbox"/> American Indian or Alaska Native
	<input type="checkbox"/> Not reported: Patient refused or not available
	<input type="checkbox"/> Unknown: Patient unsure
Method of payment (check one)	Ethnicity (check one)
<input type="checkbox"/> PI (Private Insurance)	<input type="checkbox"/> Not Hispanic or Latino
<input type="checkbox"/> MR (Medicare)	<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> MRP (Medicare and Private Insurance)	<input type="checkbox"/> Not reported: Refused or data not available
<input type="checkbox"/> MD (Medicaid)	<input type="checkbox"/> Unknown: Unsure of their ethnicity
<input type="checkbox"/> MM (Medicaid and Medicare)	
<input type="checkbox"/> MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	
<input type="checkbox"/> MS (Military Sponsored [including CHAMPUS & TRCARE])	
<input type="checkbox"/> MV (Veterans Sponsored)	
<input type="checkbox"/> SP (Self pay [no insurance])	
<input type="checkbox"/> NP (No means of payment [no insurance])	
<input type="checkbox"/> OTH (Other)	
<input type="checkbox"/> UNK (Unknown)	

Patient study ID number _____

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

Required Characteristics

Yes No NA

Histologically or cytology confirmed unresectable adenocarcinoma of the pancreas (includes subtotal resection and gross residual disease). Measurable disease is not required (see Sections 11.0 and 11.2).	___	___	___
Disease that is encompassable within standard RT fields for pancreatic cancer.	___	___	___
Adequate oral nutrition.	___	___	___
Age ≥18 years. Age = _____.	___	___	___
The following laboratory values obtained ≤14 days prior to registration. Earliest laboratory test date ___/___/_____; latest laboratory test date ___/___/_____. NOTE: These dates pertain to the following labs only.	___	___	___
• ANC ≥1500/mm³ . ANC = _____.	___	___	___
• Hgb ≥9 g/dL . Hgb = _____.	___	___	___
• PLT ≥100,000/mm³ . PLT = _____.	___	___	___
• Total bilirubin ≤3 x upper limit normal (UNL) . Bilirubin = _____; UNL = _____. NOTE: Biliary stent placement or surgical bypass should be considered prior to treatment if impending bile duct obstruction by tumor.	___	___	___
• AST ≤3 x UNL . AST = _____; UNL = _____.	___	___	___
• Creatinine ≤2.0 x UNL . Creatinine = _____; UNL = _____.	___	___	___
• Magnesium ≥LOWER limit of normal (LNL) . Magnesium = _____; LNL = _____.	___	___	___
Ability and willingness to provide informed consent.	___	___	___
Willingness to return to an NCCTG institution for follow-up.	___	___	___
ECOG performance status (PS) 0 or 1. PS = _____.	___	___	___
Negative serum pregnancy test done ≤7 days prior to registration, for women of childbearing potential only. Not a woman of childbearing potential or male (check NA) vs. negative pregnancy test date ___/___/_____.	___	___	___

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

Contraindications

Yes No NA

Evidence of metastatic disease outside of the planned radiation therapy field.	___	___	___
Distant metastases (liver or lung metastases or peritoneal spread).	___	___	___
Microscopic residual disease only.	___	___	___
Laparotomy ≤21 days prior to registration. Laparotomy not done (check NA) vs. date of Laparotomy: ___/___/_____.	___	___	___
Any of the following: • Prior anti-EGFR antibody therapy (e.g., cetuximab) or treatment with small molecule EGFR inhibitors (e.g., gefitinib, erlotinib, lapatinib) • Prior or planned concurrent systemic chemotherapy other than that included in this study or biologic therapy, or in the context of a clinical trial. • Concurrent or prior malignancy unless disease-free ≥3 years except for non-melanoma skin cancer, carcinoma in situ of the cervix, Gleason Grade <7 organ confined prostate cancer. • Any previous treatment with radiation therapy that would overlap with planned RT fields.	___	___	___
Nausea or vomiting >Grade 1.	___	___	___
Chronic use of immunosuppressive agents (e.g., methotrexate, cyclosporine, corticosteroids).	___	___	___

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Any of the following: <ul style="list-style-type: none"> • Pregnant women • Nursing women • Men or women of childbearing potential who are unwilling to employ adequate contraception during the study and for 6 months after the last treatment with panitumumab. This study involves an investigational agent whose genotoxic, mutagenic, and teratogenic effects on the developing fetus and newborn are unknown.	___ ___
Cystadenocarcinoma of the pancreas or pancreatic tumors of neuroendocrine origin.	___ ___
Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, or psychiatric illness/social situations that would limit compliance with study requirements.	___ ___
History or known presence of central nervous system (CNS) metastases.	___ ___
Clinically significant cardiovascular disease (New York Heart Association >Grade 2) including myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia ≤1 year before registration. New York Heart association classifications are provided on the NCCTG website at https://ncctg.mayo.edu/ncctg/forms/NonProtocolSpecificForms/	___ ___
Known positive test(s) for human immunodeficiency virus infection, hepatitis C virus, acute, or chronic active hepatitis B infection.	___ ___
Enteral hyperalimentation	___ ___
Current, recent (≤4 weeks prior to registration), or planned participation in an experimental drug study other than this study with the exception of studies with specific interventions intended to treat rashes associated with EGFR (e.g., N05C4).	___ ___

All responses in above section must be “No” unless specified as “NA.”

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 of consent ___/___/____.	___ ___
Authorization for use and disclosure of protected health information signed and dated. Non-USA institution only (check NA) vs. Date of authorization ___/___/____.	___ ___ ___
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician.	___ ___
Treatment must begin ≤7 days after registration.	___ ___
Pretreatment tests/procedures must be completed ≤14 days prior to registration (see Section 4.0). Earliest pretreatment test date ___/___/____; latest pretreatment test date ___/___/____. Note: The earliest pretreatment test date must be less than or equal to the earliest laboratory test date and the latest pretreatment test date must be greater than or equal to the latest laboratory test date.	___ ___
Exceptions to the above dates: <ul style="list-style-type: none"> • CT or MRI of abdomen must be done ≤ 28 days prior to registration (see Section 4.0). Earliest exception test date (mm/dd/yyyy): ___/___/____. Latest exception test date (mm/dd/yyyy): ___/___/____. 	___ ___
All required baseline symptoms must be documented and graded.	___ ___
Study drug availability checked.	___ ___
A NCCTG radiation oncologist has seen the patient and confirms the patient is a suitable candidate for this study.	___ ___

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

Patient study ID number _____

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

An optional translational research component is part of this study. There will be an option to select if the patient is to be registered onto this component (Sections 14.0 and 17.0).

	Yes	No
• Patient has given permission to give blood samples for research testing planned as part of this study.	___	___
• Patient has given permission to give tissue sample for research testing planned as part of this study.	___	___

At the time of registration/randomization, the following will also be recorded:

	Yes	No
• Patient has given permission to keep blood sample(s) for use in future research to learn about, prevent, or treat cancer.	___	___
• Patient has given permission to keep blood sample(s) for use in future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).	___	___
• Patient has given NCCTG permission to give blood sample(s) to outside researchers.	___	___
• Patient has given permission to keep tissue sample(s) for use in future research to learn about, prevent, or treat cancer.	___	___
• Patient has given permission to keep tissue sample(s) for use in future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).	___	___
• Patient has given NCCTG permission to give tissue sample(s) to outside researchers.	___	___
• Patient has agreed to be enrolled on N0392, Assessment of Patient Satisfaction with Participation in Phase II/III NCCTG Clinical Trials.	___	___

All responses in above sections may be “Yes” or “No”.

Assigned Treatment:

___ A) 5FU (or CAPCIT) + ABXEGF + GEMZAR + RT

Person registering _____ Signature
Registration Office specialist _____ initials

Physician _____ Signature
M - D - Y