

Fast Facts

ABOUT REGISTRATION FOR E5202

For clinical research associates and research nurses

How do I register a patient to this study?

ECOG Sites: Register patients by using Web registration used for all ECOG trials.

CTSU Sites: Register patients by contacting the CTSU Patient Registration Office (888-462-3009) and submit (by fax) the required patient enrollment documents.

Registration is a two-step process. Patients are registered to Step 1 prior to sending their tissue specimens to the PCO. After molecular marker analysis is performed, MD Anderson Molecular Diagnostics Laboratory will fax a copy of the E5202 Disease Recurrence Risk Status Form to the clinical site which will alert the site to register to Step 2.

When does the tumor block have to be submitted?

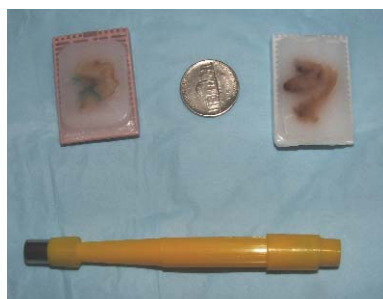
Blocks with tumor and mucosa should be submitted to the PCO within five working days of Step 1 registration and no more than 50 days post surgery in order to allow for molecular assessment. Blocks cannot be accepted after day 50 post surgery.

What constitutes an acceptable tumor specimen?

Pathologists and CRAs should follow the Pathology Submission Guidelines found in Appendix II of the protocol. Two paraffin-embedded tumor blocks containing mucosa and tumor or one block containing both types of tissue from the surgical resection specimen are required for the molecular marker analysis determination of disease recurrence risk based on 18q loss of heterozygosity (LOH) and microsatellite instability status.

What if I don't have paraffin-embedded tumor blocks?

Please contact the PCO at 312-503-3384 to determine if the alternative specimen of unstained slides can be used for analysis.



Paraffin-embedded tumor blocks. Note from the photo that the tumor sample is about the size of a nickel.

Where do I send the tissue specimen?

Tissue specimens should be logged into the ECOG Sample Tracking System and then sent to the PCO (see Sections 10.2.4.2 and 10.2.4.3 of the protocol for the contact and shipping information). The PCO reviews the specimens to ensure the required tissue has been received and then forwards the specimens to the MD Anderson Molecular Diagnostics Laboratory for the molecular marker analysis.

Sites will receive an email once the patient is registered to Step 1 that outlines the procedure required to obtain a password and use the system.

What is the risk assessment?

A molecular marker analysis is performed by the CLIA-88 compliant MD Anderson Molecular Diagnostics Laboratory to determine if the patient is at high or low risk for recurrence. The disease recurrence risk is based on 18q loss of heterozygosity (LOH) and microsatellite instability status.

When do I get the risk assessment results?

The MD Anderson Molecular Diagnostics Laboratory will fax the E5202 Disease Recurrence Risk Status Form to the submitting institution and the ECOG Randomization Desk at the ECOG Coordinating Center within four working days of receipt of the samples from the ECOG PCO.

I have not received my risk assessment results, what do I do?

Please check the ECOG Sample Tracking System to see where the specimen is in the analysis process and verify the fax and contact information is correct. Contact the ECOG Coordinating Center if you have not received the results after four working days of the specimen being sent to the MD Anderson Molecular Diagnostics Laboratory.

How do I know when to register to Step 2?

After the E5202 Disease Recurrence Risk Status Form has been received the patient should be registered to Step 2, regardless of risk assessment status. Contact the ECOG Coordinating Center if you encounter any difficulty registering the patient to Step 2.

My patient is close to Day 60 post-op, what do I do if he/she is assigned to the high-risk group?

Try to plan ahead for line placement and scheduling issues when registering the patient to Step 1 in the event the patient is assigned to the high-risk group. Contact the ECOG Coordinating Center if you are unable to start treatment by Day 60 post-operatively.



Day 60 post-op falls over a holiday weekend, what should I do?

Try to plan ahead for line placement and scheduling issues when registering the patient to Step 1 in the event the patient is assigned to the high-risk group. Contact the ECOG Coordinating Center if you are unable to start treatment by Day 60 post-operatively.

Do I need to register to Step 2 if my patient is low-risk?

Yes, all patients must be registered to Step 2 if they will be continuing in the study. If the patient was assigned high risk, he or she will be randomized between Arms A and B. If the patient was assigned low risk, he or she will be registered to Arm C.

How do I get Bevacizumab and Oxaliplatin?

Bevacizumab will be provided by Genentech Inc., and distributed by the NCI. Institutions will complete the Clinical Drug Request Form No. 986 to order bevacizumab from the NCI.

Oxaliplatin will be provided by Sanofi-Aventis and distributed by the NCI. Institutions will complete the Clinical Drug Request Form No. 986 to order oxaliplatin from the NCI. 5-fluorouracil and Leucovorin are commercially available.

Where do I get the drugs that are supplied commercially?

5-FU and Leucovorin should be available at your institution.

On January 28, 2005, the Centers for Medicare and Medicaid Services (CMS – formerly HCFA) made a special decision to cover Medicare patients enrolled in E5202 and eight other cooperative group cancer studies. Please be aware of this (Coverage Decision No. CAG-00179N), so Medicare beneficiaries considering E5202, and their families, will know that most study-related costs will be covered by Medicare.

In the event sites encounter any problem obtaining Medicare reimbursement for services to a patient enrolled in E5202, your institution’s finance personnel may wish to refer the Medicare contractor to Coverage Decision No.CAG-00179N issued January 28, 2005, which approves coverage for E5202, among other cooperative group trials. The Decision Memo from CMS, the Center for Medicare and Medicaid Services of DHHS (formerly HCFA), can be found at www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=90.

What forms do I need?

Please refer to the E5202 Forms Submission Schedule for required forms at specified intervals.

Please note: It is required to report why patients who register to Step 1 do not go on to Step 2 of the study. If your patient does not go on to Step 2, please submit all the required baseline forms as quickly as possible.

How do I complete the Surgical Screening Transmittal Form?

The E5202 Surgical Referral Form is not a mandatory Case Report Form (CRF) for submission. This optional CRF is designed to provide administrative information regarding surgeons who screen or refer patients that are registered to E5202. This is a non-monetary surgical referral credit that is for administrative reporting purposes only; periodic reports will be generated for ACOSOG and other requesting Cooperative Groups.

Section I should be completed by the Surgical CRA/RN and the form faxed to ACOSOG at 919-668-7122. The Surgical CRA/RN or Surgeon should forward the form to the Medical CRA/RN for completion of Section II.

Section II should be completed by the treating institution. For each patient that is registered to E5202, complete the ECOG Patient ID at the top of the form as well as Section II of the original form received from the referring surgeon. Fax completed form to both ECOG at 617-632-2990 and to ACOSOG at 919-668-7122.

Whom do I call if I have questions?

ACOSOG Fax: 919-668-7122

CTSU Patient Registration Office: 888-462-3009

CTSU Help Desk: 888-823-5923 or CTSUContact@westat.com

ECOG Coordinating Center: 617-632-3610 if you have questions regarding registration, scheduling conflicts, risk assessment results or forms submission.

ECOG Coordinating Center Fax: 617-632-2990

ECOG Pathology Coordinating Office (PCO): 312-503-3384 for questions regarding tissue specimens.

