

# Frequently asked Questions...

Revised CIRB Approved 5/01/07

*The Eastern Cooperative Oncology Group (ECOG) prepared this fact sheet to help you understand this cancer clinical trial.*

## **ABOUT E5202: A CLINICAL TRIAL FOR PATIENTS WITH STAGE II COLON CANCER**

### ***What is a clinical trial?***

A clinical trial is a study conducted by doctors to test new medications or new combinations of medications. This trial is called a "phase three" trial. That means that the new treatment regimen has already been tested in different doses. Now it needs to be tested to see how it compares to standard treatment.

### ***What is the purpose of this trial?***

New information about colon cancer may make it possible to identify patients who may have a high risk of developing recurrence of their cancer and to more clearly define low-risk patients who would not require chemotherapy after surgery.

There are several purposes to this trial:

- 1) To determine if certain molecular observations identified in some colon cancer cells may be used to help identify patients who are low-risk and would not require chemotherapy after surgery from those at high-risk of having a recurrence of their cancer and would be more likely to benefit from receiving chemotherapy after surgery.
- 2) To compare the effects of a combination of chemotherapy drugs given with and without a new drug called "bevacizumab" (trade name Avastin®) in patients with stage II colon cancer considered to be at high risk for recurrence of cancer.

- 3) To create a tissue repository that can be used in the future to help identify additional markers that may aid in making more personalized decisions for the treatment of colon cancer.

While we have identified some risk factors that suggest benefit from treatment after surgery, this is the first colon cancer trial which uses these factors to make treatment decisions.

### ***What is "high-risk" disease?***

Previous research has suggested that certain characteristics of the tumor cells (genetic markers) may indicate a risk for a recurrence of colon cancer. This trial is testing whether patients with specific genetic markers (high-risk markers) would benefit from receiving additional therapy while low-risk patients would receive standard follow-up care. This trial will use a sample of the tumor obtained during your colon surgery to determine whether your tumor has these markers.

### ***What should I know about the trial treatments***

Your tumor will be analyzed for two genetic "markers" or characteristics and the results will indicate the level of risk for a recurrence of colon cancer. This trial will evaluate the reliability of using this method in determining the actual level of risk for a recurrence of colon cancer.

### For Patients at Low Risk

If the risk is low, you will not receive any further treatment but will be monitored through regular office visits. Currently, this is the standard method of postoperative care for a patient with stage II colon cancer.

### For Patients at High Risk

If the risk is high, you will be randomized (meaning placed in one of two groups completely by chance). One group will receive the standard chemotherapy treatment (fluorouracil, leucovorin, and oxaliplatin, known as FOLFOX). If you are in the other group, you will receive the standard chemotherapy treatment plus the new drug, bevacizumab (trade name Avastin®).

### ***Will I be getting the most appropriate therapy for treatment of stage II disease?***

Currently, the standard method of postoperative care for patients with stage II colon cancer is close monitoring through regular office visits, but no additional therapy. In this trial, we are assessing whether those who may have the greatest risk of recurrence might benefit from additional post-operative chemotherapy, and we are more clearly defining the low-risk group that would not require additional therapy. All patients will be followed through regular office visits, but patients with high-risk markers will be randomized to receive post-operative chemotherapy.

***What are some of the side effects caused by these medications?***

Chemotherapy drugs in general cause side effects including loss of appetite, diarrhea, constipation, nausea, vomiting, numbness or tingling in hands and/or feet, hypertension, and risk of infection. There are medications available that can help control the severity of some of these side effects. Some people tolerate side effects better than others. More information on side effects can be found on the National Cancer Institute Web site at [www.cancer.gov/cancertopics/chemotherapy-and-you/page4](http://www.cancer.gov/cancertopics/chemotherapy-and-you/page4).

***What will I have to do on the clinical trial?***

If you decide to participate in this trial, you can expect the following:

- Evaluation of the tumor removed during your surgery;
- Placement of a central line for administration of chemotherapy (requires a minor surgical procedure);
- Complete physical exam;
- Blood and urine samples;
- Pregnancy test for female patients;
- Diary of aspirin use

You would most likely need to have most of these tests and procedures anyway as part of your care for colorectal cancer. Your doctor or nurse will help you set up a schedule for your tests.

***Will insurance cover the cost of this trial?***

Medicare covers the routine costs of care required in clinical trials. Many other insurers also cover these costs. Coverage may not, however, be the same from plan to plan. You or your insurance company will not be charged for the tumor testing or for bevacizumab or oxaliplatin, unless they are

approved for the treatment of stage II colon cancer during the course of your treatment. Please discuss these issues with your healthcare provider and your insurer.

***Is this trial right for me?***

To be accepted into this trial, you must have stage II colon cancer which has been surgically removed in the past 60 days. If you have not been treated with chemotherapy in the last five years for other types of cancer, you may be eligible for this trial. Men and women of all ages and ethnic groups can participate.

If you would like to know more about this trial, talk to your doctor. He or she can tell you whether this trial is right for you. If you decide to participate, your doctor will help you enroll.

***What if I change my mind after enrolling in the trial?***

You may leave the trial at any time – please discuss your concerns with your doctor.

***Would my doctor stop my participation for any reason?***

Your doctor will carefully observe your health throughout the trial. Your doctor may stop your participation if:

- Your disease progresses;
- You have serious side effects;
- New information on treating colon cancer becomes available that may affect your health or welfare.

***Who is conducting the trial?***

The Eastern Cooperative Oncology Group (ECOG) is coordinating this trial which is being conducted by the NCI-sponsored cooperative groups. ECOG is one of the largest cancer research organizations in the United States. It has a network of researchers, physicians, and healthcare professionals at public and private institutions across the country. ECOG conducts clinical trials in all types of adult cancers. It receives funding from the National Cancer Institute (NCI) and other sources. ECOG's goal is to control, effectively treat, and ultimately cure cancer. ECOG provides research results to individuals and the medical community through scientific publications and professional meetings.

***Where can I get more information?***

For more information about ECOG, visit [www.ecog.org](http://www.ecog.org). For more information about cancer and clinical trials, visit: The Coalition of Cancer Cooperative Groups:

[www.CancerTrialsHelp.org](http://www.CancerTrialsHelp.org)

The National Cancer Institute (NCI) Cancer Information Service: 1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615, [http://cancer.gov/clinical\\_trials](http://cancer.gov/clinical_trials) for clinical trial information and [http://cancer.gov/cancer\\_information](http://cancer.gov/cancer_information) for more information about cancer.

For more information about colon and rectal cancer, visit: The NCCN Cancer Treatment Guidelines [http://www.nccn.org/patients/patient\\_gls/\\_english/\\_colon/contents.asp](http://www.nccn.org/patients/patient_gls/_english/_colon/contents.asp)

