Current Clinical Trials of the Cancer Trials Support Unit (CTSU), an NCI Pilot Program

Review Article [1] | August 01, 2002
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The Cancer Trials Support Unit (CTSU) is a pilot program sponsored by the National Cancer Institute (NCI). The CTSU has two primary functions. It centralizes regulatory support for all adult Cooperative Group trials (phases I-III), thereby reducing duplication among Group members regarding credentialing, compliance with federal regulations, and institutional review board (IRB) activities. It also provides all Group members and select non-Group members with access to phase III treatment trials.

Clinical Trials Referral Resource is designed to serve as a ready reference for oncologists to help identify clinical trials that might be suitable for their patients. We hope it will also enhance accrual to clinical trials by informing practicing oncologists of ongoing protocols. Currently in the United States less than 10% of eligible adult patients are entered into clinical trials. The result is a delay in answering important therapeutic and scientific questions and disseminating therapeutic advances to the general oncology community.

It should be emphasized that including a specific trial does not imply that it is more important than another trial. Among the criteria for selection are that the trial is addressing an important question and is not expected to close in the immediate future (less than 1 year), and that initial staging or laboratory tests required for patient eligibility are widely practiced and available. Information on other protocols can be accessed via Physician’s Data Query (PDQ).* We emphasize that this is an attempt to encourage referral of patients to these trials. We are specifically not soliciting additional members for the cooperative groups, nor are we suggesting how practicing oncologists should be treating patients who are not in a study.

This month’s installment of Clinical Trials Referral Resource is devoted to current clinical trials of the Cancer Trials Support Unit, a National Cancer Institute pilot program. For patient entry information, see the individual trials.

There are currently 28 active CTSU-designated trials in the following tumor types: breast, gastrointestinal, genitourinary, adult leukemia, lung, and myeloma. The list is expanding to include other diseases such as melanoma, ovarian cancer, and sarcoma. Physicians registered with the CTSU can enroll patients in these trials even if they are not members of the Cooperative Group that is leading the trial. The CTSU will potentially allow new treatments to be available to more patients, regardless of their geographic location, because many more oncologists will now have access to these trials.

Although originally a venue for oncologists who belonged to the adult Cooperative Groups,[1] the CTSU has recently expanded to include oncologists who are not members of the Cooperative Groups. A physician in the United States who is interested in becoming a CTSU-credentialed investigator and is not a member of a Cooperative Group should complete an online Interest Form (www.ctsu.org/int_member_form.asp). A postcard version of the Interest Form can be obtained from the CTSU Help Desk by calling (888) 823-5923. However, before physicians not associated with NCI’s Cooperative Group program can enroll patients in clinical trials, they must meet standards similar to those of Cooperative Group members (ie, credentials must be verified, site preparedness must be
assessed). Non-Group members interested in trials available via the CTSU can find out how to become CTSU members by visiting the CTSU website (www.ctsu.org).

Registration With the CTSU

Registration with the CTSU allows unrestricted access to a broad menu of NCI-sponsored adult phase III Cooperative Group protocols outside of the registrant’s respective Cooperative Group. Members can receive financial reimbursement or funding credit for each patient enrolled, and credit towards Cooperative Group membership accrual requirements even when the registrant’s respective Cooperative Group does not sponsor the protocol.

Canadian investigators affiliated with a Cooperative Group who are interested in participating in CTSU trials need to register with the CTSU. Once Canadian regulatory approval of the study has been obtained, notification of this will be posted on the CTSU registered member website. At that time, the CTSU will provide a French translation of the consent and post it along with the Investigator Agreement, Qualified Investigator Undertaking, Clinical Trials Site Information, and Research Ethics Board Attestation forms on the protocol-specific page of the CTSU registered member website. For all Canadian sites, the trial may not be locally activated until required ethics and regulatory documents are completed and forwarded to the CTSU.

Conclusion

The CTSU serves as a cornerstone in the NCI’s ongoing effort to restructure its clinical treatment trials program to better serve clinical investigators in the field and their patients. By providing technical and administrative support to complement the top quality, peer-reviewed research efforts of NCI’s Clinical Trials Cooperative Groups, the CTSU is designed to help make the overall system more flexible, efficient, and cost-conscious for physicians. Doing so should assure that the NCI achieves its ultimate goal of providing new and innovative cancer treatments to more patients via carefully conducted clinical trials.

Upcoming CTSU Events

The CTSU will be present at the following upcoming conferences:

- North Central Cancer Treatment Group (NCCTG): October 8-11, 2002, Rochester, Minn
- Cancer and Leukemia Group B (CALGB): November 7-10, 2002, Tampa, Fla
- Eastern Cooperative Oncology Group (ECOG): November 16-18, 2002, Miami, Fla

CTSU Contact Information

General questions regarding the CTSU may be submitted online to ctsucontact@westat.com. The General Information number, (888) 823-5923, will handle general inquiries about the CTSU, including information about clinical studies, investigator registration, and other issues. The Patient Registrar number, (888) 462-3009, is specifically for patient enrollment and adverse event reporting.

Active Trials

**Title:** Phase III Randomized Study of Adjuvant Cyclophosphamide and Doxorubicin Versus Paclitaxel in Women With High-Risk Node-Negative Breast Cancer  
**Protocol Number:** CLB-40101  
**Participating Institutions:** CALGB  
**Contact:** CALGB Central Office, (773) 702-9171; for a complete listing of study contacts, click here

**Latest Information:** [http://www.cancer.gov/clinical_trials/](http://www.cancer.gov/clinical_trials/)

**Title:** Phase III Randomized Study of Doxorubicin and Cyclophosphamide With or Without Dexrazoxane, Followed By Paclitaxel With or Without Trastuzumab (Herceptin), Followed By Surgery and Radiotherapy With or Without Trastuzumab in Women With HER-2+ Stage IIIA or IIIB or Regional Stage IV Breast Cancer  
**Protocol Number:** CLB-49808  
**Participating Institutions:** CALGB, CTSU
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Published on Physicians Practice (http://www.physicianspractice.com)

Contact: CALGB Central Office, (773) 702-9171; for a complete listing of study contacts, click here
Latest Information: http://www.cancer.gov/clinical_trials/

Title: Phase III Randomized Study of Adjuvant Chemotherapy Comprising Standard Cyclophosphamide, Methotrexate, and Fluorouracil (CMF) or Doxorubicin and Cyclophosphamide (AC) Versus Oral Capecitabine in Elderly Women With Operable Adenocarcinoma of the Breast
Protocol Number: CLB-49907
Participating Institutions: CALGB, CTSU, EPP (Expanded Participation Project), NCCTG
Contact: CALGB Central Office, (773) 702-9171
Latest Information: http://www.cancer.gov/clinical_trials/

Title: Phase III Randomized Study of Paclitaxel and Carboplatin Versus No Adjuvant Chemotherapy After Resection in Patients With Stage IB Non-Small Cell Lung Cancer
Protocol Number: CLB-9633, RTOG-9616
Participating Institutions: CALGB, NCCTG, RTOG, EPP (Expanded Participation Project), CTSU
Contact: CALGB Central Office, (773) 702-9171; for a complete listing of study contacts, click here
Latest Information: http://www.cancer.gov/clinical_trials/

Title: Phase III Randomized Study of Paclitaxel Via One Hour Infusion Every Week Versus Three Hour Infusion Every 3 Weeks With or Without Trastuzumab (Herceptin) in Patients With Inoperable, Recurrent, or Metastatic Breast Cancer With or Without Overexpression of HER2-Neu
Protocol Number: CLB-9840
Participating Institutions: CALGB, EPP (Expanded Participation Project), CTSU
Contact: CALGB Central Office, (773) 702-9171; for a complete listing of study contacts, click here
Latest Information: http://www.cancer.gov/clinical_trials/

Title: Phase III Randomized Study of Paclitaxel and Carboplatin With or Without Bevacizumab in Patients With Advanced, Metastatic, or Recurrent Non-Squamous Cell Non-Small Cell Lung Cancer
Protocol Number: E-4599
Participating Institutions: ECOG, CTSU, EPP (Expanded Participation Project)
Contact: Jean McDonald, (617) 632-3610; for a complete listing of study contacts, click here
Latest Information: http://www.cancer.gov/clinical_trials/

Title: Phase III Randomized Study of Paclitaxel and Carboplatin With or Without Gemcitabine, Doxorubicin HCl Liposome, or Topotecan in Patients With Stage III or IV Ovarian Epithelial or Primary Peritoneal Carcinoma
Protocol Number: E-3200
Participating Institutions: ECOG, CTSU, EPP (Expanded Participation Project)
Contact: Jean McDonald, (617) 632-3610; for a complete listing of study contacts, click here
Latest Information: http://www.cancer.gov/clinical_trials/

Title: Phase III Randomized Study of Paclitaxel and Carboplatin With or Without Bevacizumab in Patients With Advanced, Metastatic, or Recurrent Non-Squamous Cell Non-Small Cell Lung Cancer
Protocol Number: E-2100
Participating Institutions: ECOG, CTSU, EPP (Expanded Participation Project)
Contact: Jean McDonald, (617) 632-3610; for a complete listing of study contacts, click here
Latest Information: http://www.cancer.gov/clinical_trials/

Title: Phase III Randomized Study of Paclitaxel and Carboplatin With or Without Bevacizumab in Patients With Squamous Cell Non-Small Cell Lung Cancer
Protocol Number: E-3200
Participating Institutions: ECOG, CTSU, EPP (Expanded Participation Project)
Contact: Jean McDonald, (617) 632-3610; for a complete listing of study contacts, click here
Latest Information: http://www.cancer.gov/clinical_trials/

Title: Phase III Randomized Study of Oxaliplatin, Fluorouracil, and Leucovorin Calcium With or Without Bevacizumab Versus Bevacizumab Only in Patients With Previously Treated Advanced or Metastatic Colorectal Adenocarcinoma
Protocol Number: GOG-0182, SWOG-G0182
Participating Institutions: GOG, SWOG, CTSU
Contact: Michael A. Bookman, ma_bookman@fccc.edu; for a complete listing of study contacts, click here
Latest Information: http://www.cancer.gov/clinical_trials/

Title: Phase III Randomized Study of Intermittent Versus Continuous Androgen Suppression in Patients With Prostate Specific Antigen Progression in the Clinical Absence of Distant Metastases After Prior Radiotherapy for Prostate Cancer
Protocol Number: CAN-NCIC-JPR7, CAN-NCIC-PR7, CTSU, SWOG-JPR7
Contact: CALGB Central Office, (773) 702-9171; for a complete listing of study contacts, click here
Latest Information: http://www.cancer.gov/clinical_trials/
Participating Institutions: NCIC (National Cancer Institute of Canada), SWOG, CTSU
Contact: Juanita M. Crook, (416) 946-2125; for a complete listing of study contacts, click [here](http://www.cancer.gov/clinical_trials/)

Latest Information:

**Title:** Phase III Randomized Study of Consolidation Therapy With or Without Strontium Chloride Sr 89 After Induction Chemotherapy in Patients With Androgen-Independent Prostate Cancer

**Protocol Number:** MDA-ID-00156, NCI-3410

**Participating Institutions:** M. D. Anderson Cancer Center

**Contact:** Shi-Ming Tu, (713) 792-2830


**Title:** Phase III Randomized Study of Oral Carboxyamidotriazole in Patients With Stage III or IV Non-Small Cell Lung Cancer

**Protocol Number:** NCCTG-NCTG-972451

**Participating Institutions:** NCCTG, EPP (Expanded Participation Project), CTSU

**Contact:** Edith A. Perez, (904) 953-7283; for a complete listing of study contacts, click [here](http://www.cancer.gov/clinical_trials/)


**Title:** Phase III Randomized Study of Exemestane in Postmenopausal Women With Resected Stage I, II, or IIIA Breast Cancer Who Have Completed Five Years of Tamoxifen

**Protocol Number:** NSABP-B-33

**Participating Institutions:** NSABP, CTSU

**Contact:** Mary Ketner, (412) 330-4624; for a complete listing of study contacts, click [here](http://www.cancer.gov/clinical_trials/)


**Title:** Phase III Randomized Study of Radiotherapy With Or Without Bicalutamide in Patients With PSA Elevation Following Radical Prostatectomy for Carcinoma of the Prostate

**Protocol Number:** RTOG-9601, RTOG-R9601, SWOG-R9601

**Participating Institutions:** RTOG, SWOG, CTSU

**Contact:** Elaine Pakuris, (215) 574-3195; for a complete listing of study contacts, click [here](http://www.cancer.gov/clinical_trials/)


**Title:** Phase III Randomized Study of Whole Breast Radiotherapy Versus Observation With or Without Optional Tamoxifen in Women With Good-Risk Ductal Carcinoma In Situ of the Breast

**Protocol Number:** CAN-NCIC-MA26, CLB-49801, RTOG-9804, RTOG-DEV-1026

**Participating Institutions:** RTOG, Memorial Sloan-Kettering Cancer Center, CALGB, EPP (Expanded Participation Project), SWOG, NCIC (National Cancer Institute of Canada), CTSU

**Contact:** Elaine Pakuris, (215) 574-3195; for a complete listing of study contacts, click [here](http://www.cancer.gov/clinical_trials/)


**Title:** Phase III Randomized Study of Neoadjuvant Total Androgen Suppression and Radiotherapy With or Without Subsequent Paclitaxel, Estramustine, and Etoposide in Patients With Localized High-Risk Prostate Cancer

**Protocol Number:** RTOG-9902, RTOG-DEV-1020

**Participating Institutions:** RTOG, University of Michigan Medical Center

**Contact:** Elaine Pakuris, (215) 574-3195; for a complete listing of study contacts, click [here](http://www.cancer.gov/clinical_trials/)


**Title:** Phase III Randomized Study of Neoadjuvant Total Androgen Suppression and Radiotherapy in Patients With Intermediate-Risk Adenocarcinoma of the Prostate

**Protocol Number:** RTOG-9910

**Participating Institutions:** RTOG, CTSU

**Contact:** Elaine Pakuris, (215) 574-3195; for a complete listing of study contacts, click [here](http://www.cancer.gov/clinical_trials/)
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Published on Physicians Practice (http://www.physicianspractice.com)

Latest Information: http://www.cancer.gov/clinical_trials/
Title: Phase III Randomized Adjuvant Study of Radiotherapy With Hormonal Therapy Versus Radiotherapy Alone Versus Hormonal Therapy Alone in Patients With High-Risk Stage III Prostate Cancer
Protocol Number: RTOG-P-0011, RTOG-DEV-1037
Participating Institutions: RTOG, CTSU
Contact: Elaine Pakuris, (215) 574-3195; for a complete listing of study contacts, click here

Latest Information: http://www.cancer.gov/clinical_trials/
Title: Phase III Randomized Study of Carboplatin and Paclitaxel With or Without Tirapazamine in Patients With Advanced Non-Small Cell Lung Cancer
Protocol Number: SWOG-S0003
Participating Institutions: SWOG, EPP (Expanded Participation Project), CTSU, Southwest Oncology Group CCOP Ordering Group, CALGB
Contact: Marj Godfrey, (210) 677-8808; for a complete listing of study contacts, click here

Latest Information: http://www.cancer.gov/clinical_trials/
Title: Phase III Randomized Study of Neoadjuvant Doxorubicin and Cyclophosphamide With or Without Filgrastim (G-CSF) in Women With Inflammatory or Estrogen Receptor Negative Locally Advanced Breast Cancer
Protocol Number: SWOG-S0012
Participating Institutions: SWOG, EPP (Expanded Participation Project), CTSU
Contact: Marj Godfrey, (210) 677-8808; for a complete listing of study contacts, click here

Latest Information: http://www.cancer.gov/clinical_trials/
Title: Phase III Randomized Study of Surgery With or Without Preoperative Paclitaxel and Carboplatin in Patients With Stage IB, II, or Selected IIIA Non-Small Cell Lung Cancer
Protocol Number: E-S9900, NCCTG-S9900, RTOG-L0015, SWOG-S9900
Participating Institutions: SWOG, ECOG, NCCTG, CTSU, RTOG, ACOSOG, M. D. Anderson Cancer Center, Southwest Oncology Group CCOP Ordering Group, NCIC (National Cancer Institute of Canada)
Contact: Marj Godfrey, (210) 677-8808; for a complete listing of study contacts, click here

Latest Information: http://www.cancer.gov/clinical_trials/
Title: Phase III Randomized Study of Docetaxel and Estramustine Versus Mitoxantrone and Prednisone in Patients With Hormone-Refractory, Metastatic Adenocarcinoma of the Prostate
Protocol Number: CLB-99808, NCCTG-S9916, SWOG-S9916
Participating Institutions: SWOG, CALGB, EPP (Expanded Participation Project), NCCTG, CTSU, Southwest Oncology Group CCOP Ordering Group
Contact: Marj Godfrey, (210) 677-8808; for a complete listing of study contacts, click here

Latest Information: http://www.cancer.gov/clinical_trials/
Title: Phase III Randomized Study of Adjuvant Androgen Deprivation Therapy With or Without Mitoxantrone and Prednisone After Radical Prostatectomy in Patients With High-Risk Adenocarcinoma of the Prostate
Protocol Number: CLB-99904, SWOG-S9921
Participating Institutions: SWOG, EPP (Expanded Participation Project), CALGB, CTSU, Southwest Oncology Group CCOP Ordering Group, ECOG
Contact: Marj Godfrey, (210) 677-8808; for a complete listing of study contacts, click here

Latest Information: http://www.cancer.gov/clinical_trials/
Title: Lung Cancer Specimen Repository Protocol, Ancillary
Protocol Number: S9925
Participating Institutions: SWOG, CTSU, NCIC (National Cancer Institute of Canada), Southwest Oncology Group CCOP Ordering Group
Contact: Marj Godfrey, (210) 677-8808

Approved Trials

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Title: Phase III Randomized Study of Carboplatin, Paclitaxel, and Radiotherapy With or Without Thalidomide in Patients With Stage III Non-Small Cell Lung Cancer  
Protocol Number: E-3598  
Participating Institutions: ECOG, EPP (Expanded Participation Project)  
Contact: Jean McDonald, (617) 632-3610; for a complete listing of study contacts, click here  
Latest Information: http://www.cancer.gov/clinical_trials/  
Title: A Clinical Trial Comparing Anastrozole With Tamoxifen in Postmenopausal Patients With Ductal Carcinoma In Situ (DCIS) Undergoing Lumpectomy With Radiation Therapy  
Protocol Number: NSABP-B-35  
Participating Institutions: NSABP, CTSU  
Contact: Mary Ketner, (412) 330-4624  
Title: Phase III Study of Fluorouracil and Leucovorin Calcium With or Without Oxaliplatin in Patients With Stage II or III Carcinoma of the Colon  
Protocol Number: NSABP-C-07  
Participating Institutions: NSABP  
Contact: Mary Ketner, (412) 330-4624; for a complete listing of study contacts, click here  
Latest Information: http://www.cancer.gov/clinical_trials/  

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