NCI’s Clinical Trials Program

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Division of Cancer Treatment and Diagnosis, NCI
NCI Clinical Trials
Prevention - Diagnosis
Treatment - Cancer Control
NCI Clinical Trials Program: multi-faceted

Extramural

• Grant mechanisms – R01, R03, R21, R37 and P01 trials in treatment, control and prevention
• Cancer Center Core grant – provides partial support for trials at NCI comprehensive cancer centers
• Research Contracts – Prevention and Treatment Trials
• SPORES (P50s) – Treatment and Prevention
• Cooperative Agreements – CCOP research bases, Cooperative Groups, Phase 1 treatment and CNS tumors (adult and pediatrics), BMT-CTN

Intramural

• Clinical Center
Clinical Trial Accrual at NCI-designated Comprehensive Cancer Centers - 2007

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>Accrual #</th>
<th>(%)</th>
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<tbody>
<tr>
<td>NCI Peer Review</td>
<td>9954</td>
<td>(20)</td>
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<tr>
<td>Investigator-initiated</td>
<td>19,131</td>
<td>(38)</td>
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<td>Cooperative Group</td>
<td>9285</td>
<td>(19)</td>
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<td>Total</td>
<td>38,370</td>
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<tr>
<td>Industry</td>
<td>11,471</td>
<td>(23)</td>
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<tr>
<td>Total</td>
<td>49,841</td>
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Welcome to caCTUS

Cancer Clinical Trial Unified System (caCTUS™) is a registry system for cancer clinical trial protocols that gives you the tools to:

- [Search for clinical trial protocols](#) submitted by members of the [caBIG™ community](#). You can view detailed protocol information such as the title, NCI and local identification numbers, study phase, study status, principal investigators, and more.
- [Submit your clinical trial protocols](#) and join our community of contributing scientists.
- [Login/register](#) to enter protocol details into the system.
Protocol Registration Data Elements:
Common Data Elements (CDEs) Identified

1. Lead Organization
2. Lead Organization Protocol ID
3. Principal Investigator
4. Sponsor
5. Protocol Title
7. Trial Type
8. Trial Phase
9. Accrual Status
10. Accrual Status date
Division of Cancer Prevention (DCP)

Number of Clinical Trials by Phase and Fiscal Year

Number of Trials

Phase 1
Phase 2
Phase 3
N/A; Other and Pilot

CTEP Therapeutics Development Program

Number of Active Trials by Phase and Fiscal Year

Number of Trials


Phase 1
Phase 2
Phase 3
Other/Pilot
CTEP Therapeutics Development Program

Number of Patients by Phase and Fiscal Year

Number of Patients

- Phase 1
- Phase 2
- Phase 3
- Other/Pilot
- Group (All Phases)
- Non-Group (All Phases)

FY2002 to FY2007
NCI Clinical Trials
Cooperative Group Program:
Focus on late phase 2 and phase 3 trials
Overview

- NCI’s Clinical Trials Cooperative Group Program (the “Groups”) is distinctive among NIH-supported clinical trials programs:
  - Consists of researchers at institutions affiliated with the Groups who jointly develop and conduct trials in multi-institutional settings
  - A clinical trials infrastructure that is continuously available to test new therapeutic strategies
  - Flexible research agenda - allows change of strategy in response to changing scientific opportunities and new discoveries
Total Sites = 1,878
2004 Data

United States
(AK & HI Inset)
by Sites
1Dot = 5 sites
CCOPs and Minority CCOPs

June 2005
NCI Cooperative Group History & Evolution

- **1955-1960**: Development of over 15 Groups, organized and operated by research grants from NCI, with the main purpose of testing new anticancer agents from the NCI’s investigational agent development program.

- **1966**: Separated from the drug development program; multidisciplinary studies begun.

- **1968**: Clinical Investigations Branch created to administer program; Cancer Clinical Investigations Review Committee was chartered.

- **1981**: Mechanism of support converted from a grant to cooperative agreement to define the involvement of NCI program staff in the coordination of Group activities.
- **1983**: Community Clinical Oncology Program initiated to provide independent funding for community physicians to participate in Cooperative Group Treatment Trials and build a network for cancer prevention and control clinical trials.

- **1987**: Cooperative Groups and select Cancer Centers were funded as Research Bases to include the development of cancer prevention & control trials

- **1990**: Minority-based CCOPs initiated

- **1999**: Clinical Trials Implementation Plan

- **2005**: Clinical Trials Working Group
NCI Cooperative Group Program
2008: 10 Groups - 9 adult and 1 pediatric

• **Multimodality:**
  - Cancer and Acute Leukemia Group B (CALGB)
  - Children’s Oncology Group (COG)
  - Eastern Cooperative Oncology Group (ECOG)
  - North Central Cancer Treatment Group (NCCTG)
  - Southwest Oncology Group (SWOG)
  - NCI of Canada – Clinical Trials Group (NCIC-CTG)**

• **Specialty:**
  - American College of Surgeons Oncology Group (ACOSOG)
  - National Surgical Adjuvant Breast & Bowel Project (NSABP)
  - Gynecologic Oncology Group (GOG)
  - Radiation Therapy Oncology Group (RTOG)

** NCIC-CTG funding limited to participation in Intergroup trials
Related NCI-sponsored Groups

- QARC – Quality Assurance Review Center
  - Provide radiotherapy quality assurance, diagnostic imaging data management, managed by CTEP

- RPC – Radiological Physics Center
  - Assures Groups that sites participating in trials deliver prescribed radiation doses, develop quality assurance procedures, managed by CTEP and RRP

- ACRIN - American College of Radiology Imaging Network
  - Trials of diagnostic imaging and image-guided therapeutic technologies, managed by the Cancer Imaging Program in the NCI Division of Cancer Treatment & Diagnosis
NCI Cooperative Group Funding

- Groups are funded by cooperative agreement
  - used by government when significant government input is advantageous to the conduct of research

- Cooperative Group Guidelines govern the relationship between CTEP and the Groups

- Terms of Award
  - Groups
    - Operations, stats, investigators, committees
  - NCI CTEP
    - Coordination, protocol review, quality assurance
  - JOINT
    - DSMBs, Meetings, Intergroups, Arbitration
NCI Cooperative Group Funding

- **Additional Cost Alternative** - Groups are permitted to accept funds from non-governmental sources for research that is not supported by the NCI
  - Industry
  - Charitable contributions

- **Public-private partnerships are valuable**
  - Permit additional research & regulatory compliance to be realized
  - However, not an infinitely extendable system as increased funds are not rapidly translatable to trained personnel at a large number of sites

- **Independence is protected**
  - NCI/Steering Committee review
  - DSMC committees
  - INDs held by Group or CTEP for phase 3 trials
  - Data withheld from company until trial is analyzed and made available to public
What types of trials?

Focus on best management of diseases, not agents

- Integrate new agents into standard regimens
- Compare two or more novel approaches to an accepted standard
- Multimodality treatments
- Predictive markers for selecting individualized therapeutic approaches
- Improving upon commercially available agents
- Pediatrics, Rare Diseases, International Collaborations
- Cancer Control & Prevention Trials
E2805: **ASSURE**

**Adjuvant** Sorafenib or Sunitinib for **Unfavorable Renal Cancer**

N = 1332 high risk patients s/p nephrectomy over 4 years

This trial compares 2 novel agents (from different companies) head to head.
NSABP B-39/RTOG 0413: A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer

Actual/Projected Accrual: 3087/4300 as of April 2008

Projected Completion Date: 4.6 years after activation-October, 2009

The trial Integrates a novel radiation therapy question into standard multi-modality care
**ECOG PACCT-1:** Program for the Assessment Of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options for Treatment: The Tailor Rx Trial

**Actual/Projected Accrual Goal:**
2921/4,800 as of February 2008

**Projected Completion:** May 2010

This trial tests a novel predictive test from a company, but this trial design would not have been done without NCI support.
**N0723:** MARVEL: Marker Validation for Erlotinib in Lung Cancer
NCCTG Study Chair: Alex Adjei
(Other participating groups: CALGB, ECOG, SWOG, NCIC)

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**Initial Registration**

- 2nd line NSCLC with specimen
- FISH Testing

**Strata**

- EGFR FISH + (~ 30%)
- EGFR FISH − (~ 70%)

**Randomize**

- Erlotinib
- Pemetrexed

**Outcome**

- 1° PFS
- 2° OS, ORR
- 1-2 years minimum additional follow-up

4 years accrual, 1196 patients

- PFS endpoint
  - Less influenced by treatment crossover
  - Will require synchronized treatment schedules, independent blinded imaging review

- Power
  - 90% to detect 50% PFS improvement favoring erlotinib in FISH+
  - 90% to detect 30% PFS improvement favoring pemetrexed in FISH−
  - > 90% to detect interaction

This trial is designed to qualify a predictive marker to individualize therapy
ECOG E4A03: A Randomized Phase III Study of CC-5013 plus Dexamethasone vs. CC-5013 plus Low Dose Dexamethasone in Multiple Myeloma with Thalidomide plus Dexamethasone Salvage Therapy for Non-responders

445 patients randomized between 2004-2006

Study Design – Randomized Phase III

Randomize

Lenalidomide 25 mg PO daily days 1-21 x 4 cycles
Dexamethasone 40 mg/day PO Days 1-4, 9-12, 17-20 x 4 cycles

Lenalidomide 25 mg PO daily days 1-21 x 4 cycles
Dexamethasone 40 mg/day PO Days 1, 8, 15, 22 x 4 cycles

A trial testing a commercial agent (dexamethasone). Results show low-dose dexamethasone improves survival compared to standard dose dexamethasone
S0518 Schema

Metastatic or Locally Advanced, low or intermediate grade Neuroendocrine carcinoma/Carcinoid

Arm 1:
Octreotide LAR
Bevacizumab

Arm 2:
Octreotide LAR
Interferon-alpha-2b

Primary Endpoint Target: Central Reviewed PFS – improvement from 6 to 9 months (HR 1.5, two-sided $\alpha=.05$, Power 90%)

Trials in rare diseases require Intergroup support
Prostate Ca Prevention - SELECT

Pre-Randomization Period

Randomized

Vitamin E + Selenium
Vitamin E + Placebo
Placebo + Selenium
Placebo + Placebo

Follow-up
Prostate cancer, other cancer, death

Calendar Year
2001 - 2004

Calendar Year
2001 - 2013
CANCER CONTROL - NCCTG N04C7: Calcium/Magnesium for Oxaliplatin Neuropathy

FOLFOX for adjuvant chemotherapy for Colon Cancer

Randomization

Placebo*  Ca/Mag Infusion

Neuropathy assessed by CTCAE augmented with additional patient reported outcomes.
Cooperative Group Awards
FY1999 to FY2007

Per-case local site reimbursement for all patients is $2,000 since year 2000

Dollars in thousands
CCOP Research Base and Prevention Trial Awards
FY 1999 to FY 2007

Dollars in Thousands

Research Base Awards
Prevention Trial Awards
CCOP & MBCCOP Awards
CTWG Initiatives

- 2007 – $5 million supplement to high accruing sites (in 2008, a supplement is anticipated for complex trials)
- 2008 – $1.6 million dollars set aside to fund Group Studies using integral/integrated markers
  - Pediatric AML study – FLT3, CEPB genes
  - 2 Cancer Control Studies – Fatigue and neurotoxicity mechanisms
In 1997, the Clinical Trials Review Committee suggested the need for change, and in 1999 the Clinical Trials Implementation Group recommended the creation of:
- Cancer Trials Support Unit (CTSU)
- Central Institutional Review Board (CIRB)

In 2005, the Clinical Trials Working Group (CTWG) created disease-specific steering committees to incorporate additional expertise in review
- Cooperative Group members
- SPOREs, Cancer Centers, basic science researchers
- Patient Advocates
- Community oncologists
Coordination of Group Phase 3 Trials

- Scientific meetings to identify key opportunities and issues
- Phase III trials based on best science
  Concepts generated by Groups, Consortia, SPORES, & others
  Concepts evaluated by multidisciplinary extramural investigators & NCI staff
- NCI protocol review is expedited in most cases
- Central IRB
  Provides expert review and speeds nationwide activation
- CTSU - All phase 3 trials open for accrual from all qualified investigators
Disease-Specific Steering Committees

- Gastrointestinal Cancer (Co-Chairs: Joel Tepper, MD & Daniel Haller, MD)
- Gynecologic Cancer (Co-Chairs: William Hoskins, MD & Gillian Thomas, MD)
- Head and Neck Cancer (Co-Chairs: Arlene Forastiere, MD, David Schuller, MD, & Andrew Trotti, MD)
- Symptom Management and Health-Related Quality of Life (Co-Chairs: Deborah Bruner, RN, PhD & Michael Fisch, MD, MPH)
- Genitourinary SC (Co-Chairs: Ian Thompson, MD, Anthony Zietman, MD, & George Wilding, MD)
- Patient Advocate SC (Co-Chairs: Susan Leigh, RN & Jim Williams, MS)
- Lung SC (In Process - TBD)
GI Steering Committee: Activities

- Reviewed 10 concepts; 3 approved, 1 pending, and 6 disapproved
  - Disease sites (pancreas, colon, esophagus, hepatocellular, rectal, neuroendocrine, GIST)
  - Therapeutic modalities included chemotherapy, VEGF inhibitors, EGFR inhibitors, radiation, & chemoembolization
  - 3 new concepts scheduled for review in May & June 2008 (2 phase III trials and 1 phase II study)

- Regular face-to-face meetings at ASCO & GI ASCO

- Pancreas cancer State of the Science meeting held in December 2007

- Hepatocellular Task Force planning a State of the Science meeting Winter 2008
GYN Steering Committee: Activities

- Committee reviews all phase III and randomized phase IIb concepts and randomized phase II concepts involving intergroup and international collaborations

- Sixteen (16) concepts reviewed to date; 10 approved

- Cervical Cancer State of the Science meeting September 27-28, 2007, Bethesda MD

- In planning – Joint GCSC/Symptom Management and Health, 2009

- In planning – New trial development for treatment of women with advanced ovarian cancer, 2009
• Head and Neck Intergroup transition to Steering Committee – December 1, 2006

• Now meeting on regular monthly schedule

• State of the Science Meeting on November 9-10, 2008:
  *Squamous Cell Head & Neck Cancer and the Human Papillomavirus*

Four Task Forces:
  – Previously Untreated, Locally Advanced Disease
  – Metastatic-Recurrent Disease
  – Rare Tumors
  – Tumor Biology & Imaging
SxQOL SC: Activities

- Monthly teleconferences
- Reviewed 7 concepts: 2 approved, 1 needed revision, and 4 disapproved
  - Symptoms include chemotherapy rash, nausea and vomiting, radiation dermatitis, weight loss and fatigue
- Regular yearly face-to-face meeting
- In development:
  - Scouting and Development WG
  - SOTS WG
  - Drug Development WG
Coordination of Group Phase 3 Trials

- Scientific meetings to identify key opportunities and issues
- Phase III trials based on best science
  Concepts generated by Groups, Consortia, SPORES, & others
  Concepts evaluated by multidisciplinary extramural investigators & NCI staff
- NCI protocol review is expedited in most cases
- Central IRB
  Expert review, decreases redundancy, and aids in nationwide activation
- CTSU - All phase 3 trials open for accrual from all qualified investigators

Network of all NCI-registered investigators
CIRB Profile

- Number of Total Enrolled Institutions 329
  - Number of Institutions enrolled in Adult only CIRB 194
  - Number of Institutions enrolled in Pediatric CIRB only 53
  - Number of Institutions enrolled in both Adult and Pediatric CIRB 82
  - Number of NCI Designated Cancer Centers 39

- Number of Studies Available for Facilitated Review 183
  - Number of Studies Available for Facilitated Review (Open/Closed to Accrual) 131/52
CIRB Studies Reviewed Since Inception

- Total Number of Studies Reviewed Since Inception: 212
  - Adult (01/01/01 to present) 138
  - Pediatric (11/22/04 to present) 74
CTEP High Accruing Institutions

- Top 10 Most Active Institutions (# of subjects accrued)
  - 80% enrolled in the CIRB Initiative
- Top 50 Most Active Institutions
  - 56 % enrolled in the CIRB Initiative
Coordination of Group Phase 3 Trials

- Scientific meetings to identify key opportunities and issues
- Phase III trials based on best science
  - Concepts generated by Groups, Consortia, SPORES, & others
  - Concepts evaluated by multidisciplinary extramural investigators & NCI staff
- NCI protocol review is expedited in most cases
- Central IRB
  - Provides expert review and speeds nationwide activation
- CTSU - All phase 3 trials open for accrual from all qualified investigators
**FEATURED PROTOCOL**
*June 2008*

**Protocol:** CALGB-40101  
**Group:** CALGB  
**Type:** Breast Cancer

**Protocol Updates**

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<tr>
<th>DATE</th>
<th>PROTOCOL</th>
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<td>ACOSOG-Z1041</td>
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**CTSU ANNOUNCEMENTS**

CTSU Regulatory and General Help Desk (1-888-823-5923) and the CTSU Patient Registrar hours of operation will be 9 AM - 5:30 PM, Eastern Time, Monday - Friday (excluding holidays). **Patient Registrations received after 5 PM will be processed the following business day.**

**CHECK SITE ROSTERS:** CTSU members can check their institutional rosters for CTSU and all other adult Cooperative Groups by accessing the RSS page using the RSS tab. PMB investigator status is also available on the RSS page.
Wider Involvement

- CTSU members (all Group sites)
  - Major cancer centers, university hospitals, community hospitals, military hospitals, private clinics
- Site expansion
  - CTSU Independent Clinical Research Sites (CICRS)
  - 44 contracts covering 73 sites
- National Network
  - Consolidated roster from all Cooperative Groups
  - Centralized database of sites and investigators
  - 1,200 + active institutions
  - 7,000 + active investigators
  - 11,000 + active associates (site coordinators, CRAs, etc.)
- NEW: Cancer Research Network
  - Studies from other NCI-sponsored trials networks (other than Groups) are now being placed on the CTSU to enable broader participation
# CTSU Menu of Trials

<table>
<thead>
<tr>
<th>Cancer Site / Type</th>
<th>Active</th>
<th>Closed</th>
<th>Active and Closed</th>
<th>In Development</th>
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<td>17</td>
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<td>3</td>
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<td>Sarcoma</td>
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<td>Head and Neck</td>
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<td>GI Stromal Tumor</td>
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<td><strong>Total</strong></td>
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<td><strong>75</strong></td>
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Welcome to the Oncology Patient Enrollment Network (OPEN) Portal system

OPEN is the web-based registration system for patient enrollments onto NCI-sponsored Cooperative Group clinical trials. The system is integrated with the CTSU Enterprise System for regulatory and roster data, and with each of the Cooperative Groups’ registration/randomization systems for patient registration/randomization. OPEN provides the ability to enroll patients on a 24/7 basis.

In order to enroll patients via OPEN, you must be affiliated with at least one institution and carry the role of “registrar” at the institution(s). If you have questions about this please contact the CTSU Help Desk at 1-888-623-6823.

Training and Demonstration Materials:

- OPEN Portal User Guide. This user guide has a linkable Table of Contents that will bring you to any topic you choose, or you can scroll through and/or print the entire guide.

- OPEN Portal Demo Video. View this 10-minute video that will walk you through a basic patient enrollment using OPEN.

Useful links and updates:

- Need a CTSU AMS Account?
- CTSU Members Site
- Protocols now available in OPEN
CTSU Accomplishments

1. Increased speed of trials completion
   - Many more Intergroup trials than ever before (consistent with Steering Committee approach)
   - High accrual rates via CTSU, especially 2004-present
     - Impressive benefits for certain Groups/Diseases (ECOG, CALGB, NSABP/myeloma, renal, breast)
     - Predominance of breast cancer accruals
     - 73 non-Group affiliated sites – Could evolve into mechanism for low accruing group sites to develop track record and improve (CTWG recommendation)

2. More cost-effective, user-friendly, regulatory support system (RSS)
   - Reduces redundancy and duplication (RSS)
   - Promotes consistency for investigators/sites (RSS, CDEs)
   - Shift cost/workload burden from Groups to centralized CTSU
   - All phase 1-3 trials performed by Groups do site/investigator registration through CTSU

3. Remote Data Capture - Measures of success
   - Groups have produced a White Paper agreeing that the entire system should migrate to a single, RDC system - CTSU and Groups working together with caBIG to bring a single web-based system to all NCI clinical trial sites
Group Phase 3 Trials – an integrated, priority-driven system

- Scientific meetings to identify key opportunities and issues
- Phase III trials based on best science
  Concepts generated by Groups, Consortia, SPORES, & others
  Concepts evaluated by multidisciplinary extramural investigators & NCI staff
- NCI protocol review is expedited in most cases
- Central IRB
  Provides expert review and speeds nationwide activation
- CTSU - All phase 3 trials open for accrual from all qualified investigators

State of the Science Meetings
Disease-specific Steering Committees
COOP. GROUPS
CCOPs/Advocates
CONSORTIA,
SPORES, CCs
NCI Protocol Review Committee
Central IRB
Cancer Trials Support Unit (CTSU)
Network of all NCI-registered investigators
Communication
Auditing
Educating & Training
Cooperative Groups: Challenges for the future

- Flat budgets: Efficiency, Prioritization, Partnerships
- Molecular classification of diseases: Screening component to trials, reproducible assays, tissue and serum banks
- Outsourcing by industry: stress reasons to test agents in the U.S. population, partner with international groups
- Rising costs: leverage technology - common data elements and forms, on-line registration and data capture, remote audits, and long distance learning
- Advocacy/community partnerships: early inclusion, support for investigators, improved Congressional funding