



NCCCP

NCI Community Cancer Centers Program – Clinical Trials Component

NCI Clinical Trials Advisory Committee

December 8, 2008

Andrea Denicoff, RN,MS, ANP
Nurse Consultant
Cancer Therapy Evaluation
Program, Division of Cancer
Treatment & Diagnosis



NCCCP: Clinical Trials Goals



- Increase community connections
 - Emphasis: increase minority / underserved participation
 - Partner w Cancer Centers, Academic Ctrs, Industry, etc
- Broaden clinical trial types
 - Treatment
 - Cancer Control and Symptom Reduction
 - Prevention
- Expand complexity of trials
 - Early phase trials
 - Multimodality capacity (i.e., RT+ surgery + chemo)
 - Translational type trials (specimen submission-rich)

Timeline: Major Activities & Metrics

Year 1 (July 1, 2007- June 30, 2008)

- Increase types of trials open
- Implement screening log
- Increase # of physicians participating in CT
- Investigate new partnerships
- Investigate & plan programs to increase minority / underserved participation
- Develop timelines for protocol activation
- Develop or improve communications in cancer center
- Perform baseline self-assessment survey
- Assess navigator's outreach needs/abilities

CT Subcommittee Progress: Year 1



- Conducted survey of clinical trial activity at each site
- Surveyed sites regarding use of patient navigators and shared job descriptions
- Linked minority / underserved recruitment efforts with disparities subcommittee (cross-fertilization effort)
- Clinical Trials 101 webinar developed with disparities subcommittee and OCE
- Developed first draft of trial screening log to test
- Initially identified 3 Cooperative Group trials for sites to participate in as a network
- Establishing relationships with NCI-Designated Cancer Centers

Challenges & Strategies: Year 1

CHALLENGES	STRATEGIES
CT Insurance coverage →	Billings, MT & sites collaborating w ASCO
Access to early phase trials →	Assessing infrastructure needs to work w/ Ca Ctrs
Collection of race & ethnicity data →	Providing education
Awareness of & referral to trials by other physicians →	Provide clinical trials training to site personnel to create positive CT culture & MDs to engage other specialties re: CTs

Timeline: Major Activities & Metrics

Year 2 (July 1, 2008 – June 30, 2009)



- Open at least 1 phase 2, specimen acquisition-rich trial
- Demonstrate capacity to do multi-modality trials
- Design, analyze & implement plan to increase pt participation
- Increase minority accrual by >5%
- Demonstrate improvement in protocol/IRB timelines
- Increase number of collaborations
- Participate in formal program evaluation

CT Subcommittee Progress: Year 2



- 4 Working Groups were established to divide tasks into manageable efforts:
 1. Clinical Trial Portfolio
 2. Clinical Trial Screening Log
 3. Minority / Underserved Accrual
 4. Best Practices

CT Subcommittee Working Group:

1. Clinical Trials Portfolio WG



- Goals:
 - Identify trials for NCCCP sites to participate that meets NCCCP goals
 - Share strategies on trial selection & accrual
- Progress:
 - Sites accruing to 5 selected trials, including a cancer control trial.
 - Sites share accrual strategies- both positive & negative

CT Subcommittee Working Group:

2. Clinical Trial Screening Log



- Goals:
 - Develop user-friendly, web-based trial screening log for sites
 - Work with CBIIIT experts to develop on-line tool that could lend itself to broader caBIG use
- Progress:
 - Defined “Screened Patient” for each trial
 - Broadened initial screening log to capture accrual data
 - Screening log data informs the sites of patient and physician barriers to participation

NCCCP Clinical Trial Screening Log

NCCCP CT Screening Log — Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Refresh Mail Print W Yellow Blue People

Address <https://cabig.nci.nih.gov/ncccp-ct-screening-log> Go

NATIONAL CANCER INSTITUTE National Cancer Institute U.S. National Institutes of Health | www.cancer.gov

caBIG™ Cancer Biomedical Informatics Grid™ search

Home

Getting Connected

Learn Key Concepts

Find Tools

Data Sharing

Getting Support

Enterprise Support Network

Training Portal

About caBIG™

Events & Calendar

Workspaces & SIGs

Domain Workspaces

Clinical Trials Management Systems

Integrative Cancer Research

In Vivo Imaging

Tissue Banks and Pathology Tools

Cross Cutting Workspaces

Architecture

Vocabularies & Common Data Elements

home » ncccp ct screening log

NCCCP CT Screening Log

The Clinical Trial Screening Log is an effort to capture the screening barriers and issues related to enrolling patients to clinical trial protocols. The NCCCP Clinical Trial Subcommittee has created this web-based log and has agreed to provide a Point-of-Contact from each site to complete the log for each patient they screen to the three participating protocols: NSABP B-42; CALGB80405; ECOG 1505; The data captured for your site will be presented back to your site in an Excel spreadsheet to allow you to share the data amongst your organization at quarterly intervals. Your data will also be included in an aggregated format to inform the work of the subcommittee.

Please answer all of the questions on the following pages. You will be provided a worksheet that has all the questions and answer sets to facilitate your organizations data collection practices. Please take your time and complete each item as carefully and fully as possible for each patient screened to one of the three identified protocols. The questions are grouped in sections. As you complete each section you will select the "Next" button at the bottom of the page to progress to the next set of questions. There are four sections with 17 questions in total to answer. Once you have completed all the questions, select the "Submit" button at the bottom of the page. Once you select "Submit" you will be given an opportunity to check your answers. If you missed a question or need to change an answer you will be given a link to take you back to the log and complete or change any information necessary. Once you are satisfied with the results you will be asked to select "Submit" one final time. Once you select "Submit" from the final answer check page the log will be considered complete and will no longer be available to you. You must complete the entire assessment and submit it in one setting, as the system is not designed to save as you go.

If you have questions please contact Diane St. Germain at dstgermain@mail.nih.gov

If you need support for technical difficulties please contact:

NCICB Application Support
Telephone: 301-451-4384 or toll free: 888-478-4423

Trusted sites

CT Subcommittee Working Group: Clinical Trial Screening Log

Part 4: Protocol Screening -- Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites

Address <https://cabig.nci.nih.gov/ncccp-ct-screening-log/part-3-protocol-screening-methods/getNextPage>

Google

Go Bookmarks PageRank 21 blocked Check AutoLink AutoFill Send to

Cross Cutting Workspaces

- Architecture
- Vocabularies & Common Data Elements
- Strategic Level Workspaces
 - Data Sharing & Intellectual Capital
 - Documentation & Training
 - Strategic Planning
- Management Systems
- Templates & Forms
- Quick Links
 - National Cancer Institute
 - NCI Center for Bioinformatics
 - NCICB GForge
 - Application Support

Prior therapy

Time requirement from surgery or therapy

Co-morbidities

N/A

13) If the patient was eligible but declined participation, indicate the patient-related reason:
(Select all that apply)

- No desire to participate in research
- Preference for standard treatment
- Patient preferred another trial
- Lack of awareness/education about trials
- Perceived side effects / toxicities too great
- Cultural / religious issues
- No insurance coverage
- Has insurance but reimbursement denied
- Financial concerns/ indirect costs (work, etc)
- Travel & transportation issues
- Social issues (Housing, childcare)
- Mistrust of research
- Family member influenced against trial participation
- Patient did not provide a reason
- Language barrier
- N/A

14) If there was a language barrier, indicate the language spoken:

- Spanish
- French

Done

CT Subcommittee Working Group: Clinical Trial Screening Log Results

11/08

02/08

Screening Trial	Number of patients screened
WFU-07-02-03 (Cancer Control in CLL)	84
Tailor Rx (Adj Breast Ca)	24
NSABP B-42 (Breast ca)	157
ECOG 1505 (Adj NSCL Ca)	29
**CALGB 80405 (Met Colon Ca)	36
Total Screened	330
Total Accrued	75
Ethnicity captured	251/330
Race captured	300/330
Gender captured	321/330
Patient navigators that assisted with screening patients	16/330

Data from 2/1/08-11/14/08

** closed to accrual for scientific advance

CT Subcommittee Working Group:

3. Minority / Underserved Accrual



- Goals:
 - Identify promising practices to enhance participation of minorities and underserved in clinical trials
 - Share successful strategies
- Progress:
 - All sites connected with CIS and Received Demographic Mapping
 - Shared Minority/Underserved Outreach Efforts
 - Conducting SWAT analysis on minority accrual efforts for site-specific populations
 - Linking sites with similar minority populations for partnering & mentoring
 - Planning webinar on cultural sensitivity

CT Subcommittee Working Group:

4. Best Practices



- **Goals**
 - Identify clinical trial best practices that serve to provide enhanced efficiencies and improve operations of site clinical trials infrastructure
- **Progress**
 - Surveying members to identify most pressing area to begin first, such as working with IRBs and activating trials, staff ratios of CRAs & RNs
 - CHI developing a hospital system-wide clinical trial pathway to share with WG

Timeline: Major Activities & Metrics

Year 3 (July 1, 2009 – June 30, 2010)



- Increase overall annual accrual
- Increase minority accrual by >15%
- Increase number of open trials in all 3 domains
- Improve protocol/IRB approval timelines
- Demonstrate quality data via an audit
- Increase number of staff dedicated to CT
- Repeat self-assessment survey & compare to baseline
- Prepare report on effective methods that led to success
- Participate in formal program evaluation

NCCCP Clinical Trials Subcommittee



- **Chairs:**
 - Dr. Steve Grubbs (Christiana, Medical Oncologist)
 - Dr. Mark Krasna (CHI, Surgical Oncologist)
 - Ms. Maria Gonzalez (St. Joe/Orange, Clinical Trials Office Manager)
- **Process:**
 - Monthly conference calls of Chairs with NCI to plan subcommittee agenda
 - Monthly call with entire subcommittee and each site has at least one member, often 2 participate- such as PI and lead RN/CRA

NCI Clinical Trials Advisory Team to NCCCP



- DCTD
 - Jeff Abrams, MD
 - Andrea Denicoff, RN, MS, ANP
 - Jo Anne Zujewski, MD
- DCP
 - Wortia McCaskill-Stevens, MD, MPH
 - Diane St. Germain, RN, MS, CRNP
- CBIIT
 - Brenda Duggan, RN, BSN
- OCE
 - Annette Galassi, RN, MA, ANP
 - Rose Mary Padberg, RN, MS
- CARRA / Patient Advocates
 - Yvette Colon
 - Francine Huckaby

CT Subcommittee Working Group: Clinical Trials Portfolio WG



- Working Group Chairs
 - Lawrence Wagman – St. Joe/Orange
 - Steve Grubbs – Christiana
- Members
 - Andrea Denicoff – NCI
 - Wortia McCaskill-Stevens - NCI
 - Donna Bryant – OLOL
 - Slavisa Gasic – Ascension
 - Nancy Sprouse – Spartanburg
 - Lawrence Wagman – St. Joe/Orange
 - Camille Servodidio – Hartford
 - Louisa Hayenga – Ascension
 - Michaela Sherbeck – CHI
 - Thelma Kempista – Christiana
 - Dr. Raul Lugo – Spartanburg

CT Subcommittee Working Group: Clinical Trial Screening Log



- Working Group Chairs:
 - Maria Gonzalez – St. Joe/Orange
 - Donna Bryant – OLOL
- Members:
 - Diane St. Germaine – NCI
 - Brenda Duggan – NCI
 - Andrea Denicoff – NCI
 - Donna Bryant – OLOL
 - Lisa Koch – CHI
 - Rita Kaul – CHI
 - Tammy Brown – Christiana
 - Pam Williams – Spartanburg
 - Nancy Sprouse – Spartanburg
 - Nicole Gatens – Ascension

CT Subcommittee Working Group: Minority / Underserved Accrual



- Working Group Chairs:
 - Dr. Jay Harness – St. Joe Orange
 - Pam Williams – Spartanburg
- Members
 - Wortia McCaskill-Stevens – NCI
 - Diane St. Germain – NCI
 - Annette Galassi – NCI/CIS
 - Francine Huckaby – Patient Advocate/ CARRA
 - Deb Hood – CHI Spartanburg
 - Wanda Kay North – St. Joe/Candler
 - Donna Bryant – OLOL
 - Kathy Wilkinson – Billings
 - Polly Jones – Ascension
 - Amy Starling – Ascension
 - Maria Gonzalez – St. Joe/Orange
 - Raul Lugo – Spartanburg

CT Subcommittee Working Group: Best Practices



- **Working Group Chairs:**
 - James Bearden & Tricia Griffin – Spartanburg
 - Mark Krasna – CHI
- **Members:**
 - Rosemary Padberg – NCI
 - Kristen Gowan – CHI
 - Loren Tschetter – Sanford
 - Bob Siegel – Hartford
 - James Bearden – Spartanburg
 - David Church – Spartanburg
 - Connie Wittman – CHI
 - Kathy Wilkinson – Billings
 - Heather Gipson – Ascension
 - Debby Baumgarten – Ascension
 - Kandie Dempsey – Christiana
 - Maria Gonzalez – St. Joe/Orange
 - Nancy Sprouse – Spartanburg
 - Donna Bryant – OLOL
 - Christie Ellison – Sanford
 - Christy Fleming – Spartanburg
 - Sarah Osen – Billings
 - Tammy Brown – Christiana



NCI COMMUNITY CANCER CENTERS PROGRAM

[NCCCP HOME](#)
[ABOUT NCCCP](#)
[PILOT GOALS](#)
[MEDIA CENTER](#)
[RELATED PROGRAMS](#)

Quick Links

[Note from the
NCI Director](#)
[Participating Pilot
Sites](#)
[Frequently Asked
Questions](#)
[Contact
Information](#)


The NCI Community Cancer Centers Program (NCCCP) is a three-year pilot program to test the concept of a national network of community cancer centers to expand cancer research and deliver the latest, most advanced cancer care to a greater number of Americans in the communities in which they live.

The pilot program is designed to encourage the collaboration of private-practice medical, surgical, and radiation oncologists, with close links to NCI research and to the network of 63 NCI-designated Cancer Centers principally based at large research universities.

The NCCCP seeks to:

- Bring more Americans into a system of high-quality cancer care
- Increase participation in clinical trials
- Reduce cancer healthcare disparities
- Improve information sharing among community cancer centers