NCI COMMUNITY CANCER CENTERS PROGRAM

HELEN F. GRAHAM CANCER CENTER

CHRISTIANA CARE HEALTH SYSTEM

Monitoring Clinical Trial Accrual Utilizing The NCCCP Web Based Tracking Tool

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Introduction

- The NCI Community Cancer Centers Program (NCCCP) is a three year pilot project with goals of advancing cancer care and expanding cancer research in the community setting. The NCCCP Network consists of 10 institutions with 16 geographically diverse community hospitals charged with multiple goals including increasing overall accrual and promoting underserved population participation to clinical trials. A web based trial screening and accrual log tool has been created to collect real time network trial activity. The log captures site specific but screened patient deidentified demographics, method of screening, and trial entry outcome including reasons for accrual failure.

Methods

- The Wake Forrest University CCOP Research Base WFU 07-02-03 cancer control trial was selected by the Network for accrual study. This randomized double-blinded placebo controlled trial assessed the effect of CVT-E002 (North American Ginseng Extract) on acute respiratory illness in patients with Chronic Lymphocytic Leukemia (CLL). The Network participated and collected screening data during the 61 day enrollment period from 11/1/08 to 12/31/08.

Results

- The trial achieved full enrollment of 293. 427 CLL patients were screened and entered on the NCCCP log. 80% of screening was performed by nurse/CRA chart review. Screening demographics are listed in Table 1. NCCCP sites entered 63 on trial (22% of trial total accrual) and provided 42% of the CTSU accrual. 15% of all NCCCP screened patients were enrolled.
- 218 (51%) of screened patients were deemed trial eligible and 209 (49%) ineligible. 63 (29%) of eligible entered the trial. Reasons for no enrollment in the other 155 (71%) are listed in Table 2. 209 (49%) were ineligible for reasons listed in Table 3.

Table 1
Screened Patient Demographics

AGE	Range	32-95 years
	Median	70 years
SEX	Female	40%
	Male	60%
RACE	White	94%
	African American	5%
	Other	1%
ETHNICITY	Hispanic/Latino	3%
	Non Hispanic	97%

Table 2
Screened Eligible Not Entered on Trial
(n=153)

Patient Declined (n=141)	
No Desire for Research	55%
Not Able to Contact Patient	18%
Travel/Transportation Issues	14%
No Reason Given	9%
Perceived Excess Toxicity	3%
Social Reasons	1%
Physician Declined (n=12)	
Physician Time Constraints	25%
Other	75%

Table 3
Screened Trial Ineligible (n=209)

Prior Therapy	50%
Co morbidities	22%
Reason Not Reported	17%
Time to Entry Too Short	5%
Abnormal Labs	3%
Performance Status	3%

Conclusions

- The NCCCP clinical trial screening log successfully captures real time clinical trial participation data from a diverse network of clinical trial sites. This data base will allow future analysis of individual clinical trial, site, and network accrual barriers that will help create evidence-based strategies to increase clinical trial participation of eligible patients.