

# Community Clinical Oncology Program

## Enrollment Data Analysis Project: Trials Activated 2000 - 2010

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# Cancer Prevention and Control Clinical Trials

## Cancer Prevention Trials Considered:

- All the Large Trials ( $n > 2,000$ ) have been Removed
- Smaller Trials Included

## Cancer Control Trials Considered:

- Pilot Feasibility Studies
- Randomized Phase II
- Randomized Phase III
- Occasional Observational Study

## CCOP Analysis Factors Complementary to CTEP Analysis:

- Same Start Dates for the Trials
- Same Criteria for Accrual Completion

# Cancer Control Trials Differ from Treatment Trials

Endpoints are not Survival, or Disease Response

- Symptom (Nausea, Neuropathy, Pain, Mucositis, etc) Response
- Incidence Cancer or Pre-neoplasia for Smaller Prevention Trials

Duration of Intervention & Follow Up Shorter

- Symptom Intervention 4-8 weeks
- Occasional Cross-over Assessment

Simpler Design

Implementation Different

- Not Always Disease Specific; Bolus Recruitment

Drug Supply & Distribution not Provided

- RBs Identify Supply, Placebo, Distribution

# 2000 – 2010 Analysis Project

## Analysis #1

- How Many Clinical Trials Activated between January 1, 2000 and December 31, 2010 Complete Accrual?

## Analysis #2

- How Well Do the CTEP Slow Accruing Guidelines Work to Predict CCOP Studies that Will Not Complete Accrual?

All Data is based on Protocol Activation Date

# DCP Analysis #1

## How Many Clinical Trials Activated between January 1, 2000 and December 31, 2010 Complete Accrual?

Total Studies = 171	No. of Trials
<b>Accrual Ongoing</b>	<b>11</b>
Successful Accrual: $\geq 90\%$ accrual at the time of this analysis	<b>4 (37%)</b>
Inadequate accrual: $<90\%$ accrual at this time of this analysis	<b>7 (63%)</b>
<b>Accrual Completed or Study Closed</b>	<b>160</b>
Successful Accrual: $\geq 90\%$ accrual at the time of study closure	<b>102 (60%)</b>
Inadequate accrual : $<90\%$ accrual at this time of study closure	<b>58 (40%)</b>
<b>Reasons for <math>&lt;90\%</math> Accrual at this time of analysis</b>	
Drug Supply Issues, out of our control	<b>14</b>
External Information (e.g., appropriate early closure; Interim monitoring for safety and closed early (unusual toxicity, and possible futility but not futile for poor accrual))	<b>8</b>
Inadequate Accrual Rate	<b>36</b>

# Results

## DCP Results:

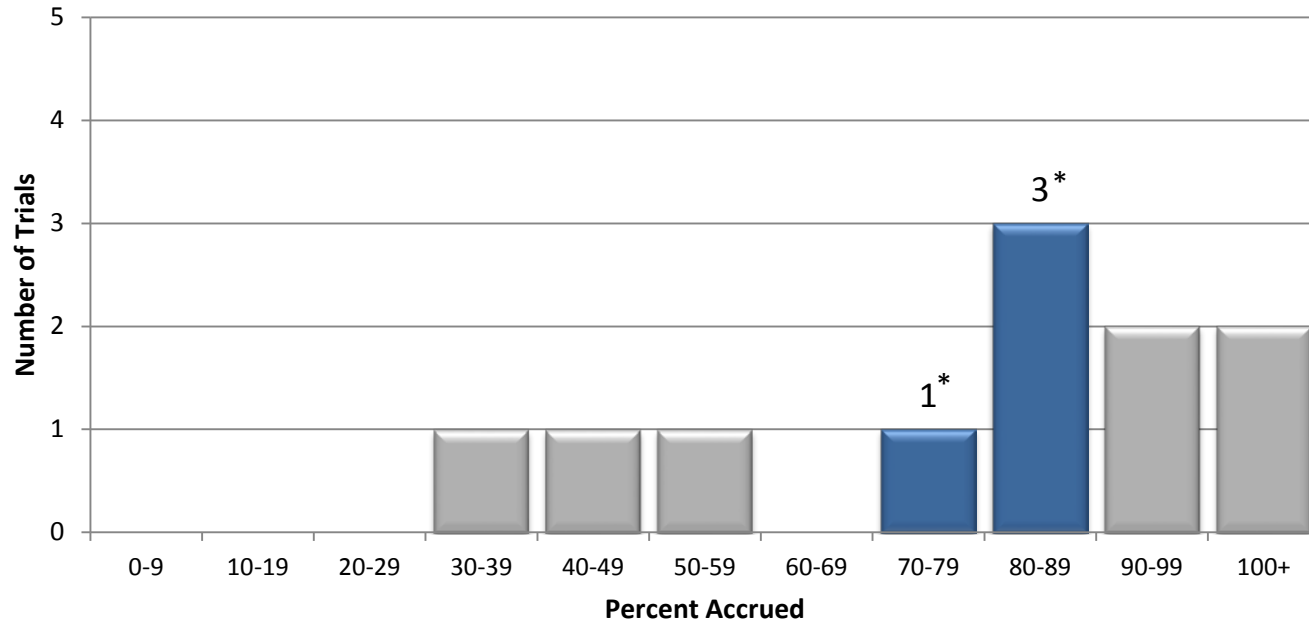
- At Least 62% (4+ 102) of Trials Complete
- **21%**, 36 of the 171 Trials Activated from 2000 to 2010 had Inadequate Accrual

## CTEP Results:

- Original Analysis
  - **21.5%**, had Inadequate Accrual
- Updated Analysis
  - **21%** had Inadequate Accrual

# DCP Analysis #1

## How Many Clinical Trials Activated between January 1, 2000 and December 31, 2010 Complete Accrual?



Histogram of current percent accrued for 11 trials that are not closed to accrual. \*4 DCP projects with current accrual over 75% are anticipated to complete.

# 2000 – 2010 Analysis Project




- Analysis #1
  - How Many Clinical Trials Activated between January 1, 2000 and December 31, 2010 Complete Accrual?
- **Analysis #2**
  - **How Well Do the CTEP Slow Accruing Guidelines Work to Predict CCOP Studies that Will Not Complete Accrual?**
- All Data is based on Protocol Activation Date



# CTEP Slow Accruing Guidelines

Based Upon CTEP Data, No Trial Completed Accrual if in Quarter 5 & 6, the Accrual Rate was < 20%

## Slow Accruing Guidelines:

- If Accrual Rate is < 20%  Stop Trial
- If  $20 < AR < 50\%$   Revise Accrual Plan  
Consider Revisiting Sample Size  
Address Other Protocol Issues
- If Accrual Rate is > 50%  Continue Trial

## DCP Analysis #2

# How Well Do the CTEP Slow Accruing Guidelines Work to Predict CCOP Studies that Will Not Complete Accrual?

### Phase III Drug Intervention Trials

Categories	Number of Studies
<u>If &gt; 50% of accrual rates of the last approved protocol document prior to activation</u> ; ignore as they are on target	18
<u>If 20-50% of accrual rates of the last approved protocol document prior to activation</u> , this group will need to see the quarter 8 accrual rate (is that >50% or not)	6
<u>If &lt; 20% of accrual rates of the last approved protocol document prior to activation</u> , they should have been closed, but probably not.	20 <b>Note: 16 of the 20 studies eventually reached its Accrual goal &gt;90%.</b>
	<ul style="list-style-type: none"> <li>10 actually completed accrual faster than expected (e.g., planned duration based on monthly accrual goal)</li> </ul>
	<ul style="list-style-type: none"> <li>6 took longer than plan                             <ul style="list-style-type: none"> <li>Avg. time = 10 additional months</li> <li>Med. Time of 7 additional months</li> <li>Range = 3.6 – 26 months</li> </ul> </li> </ul>

NOTE: Reviewed 44 of the 86 Phase III drug trials , awaiting protocol files from off-site storage.

# Next Steps

## Ongoing Analysis:

- Continue to Review Trials with Respect to Slow Accruing Guidelines
- Cancer Control Studies Have Some Different Needs or Issues
- Consider Complementary Guidelines for CCOP Studies
- Studies with Behavioral Interventions, May Need Different Guidelines