NCI Community Oncology Research Program (NCORP)

Leading the Charge for a New Generation of Clinical Trials

SWOG NCORP Research Base Clinical Trials Workshop
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NIH NATIONAL CANCER INSTITUTE
Today’s Discussion

“NCORP is so massive, how does it all fit together?”

• New Generation of Clinical Trials
• Community/Academic Investigators
“...Perhaps more for cancer than for any other disease, state-of-the-art care is defined through the results of clinical trials...”

Managing a Health Care Alliance
Kaluzny, et al, 1996
NCI Community Oncology Research Program (NCORP)

**Clinical Trials** for prevention, control, health-related quality of life, comparative effectiveness, and screening

**Accrual** to National Clinical Trials Network (NCTN) treatment and imaging trials

**Cancer care delivery research** focused on patient-provider and organization-level influences on cancer outcomes

Incorporation of **cancer disparities research** into clinical trials and cancer care delivery research
Drivers of a New Generation of Clinical Trials

- Biology (lab and clinic)
- Technology
- Economics and Demographics
Research Agenda for Cancer Prevention, Control & Screening Trials

- Mechanisms of cancer-related symptoms
- Biomarkers of risk for treatment-related toxicities
- Post-treatment surveillance
- Management of precancerous lesions
- Enhance accrual of racial/ethnic and other under-represented populations
- Overdiagnosis
NCI Community Oncology Research Program (NCORP)

Symptom Science Research Priorities:

- Cognitive impairment
- Neurotoxicity
- Cardiovascular toxicity
- Fatigue
- Cancer Specific Pain

- Randomized Phase II of Memantine & WBRT w/wo Hippocampal Avoidance in Brain Metastases
- Randomized Phase II/III Trial of Prophylactic Cranial Irradiation w/wo Hippocampal Avoidance for SCLC
Symptom Science: Cognition

1. Intensity Modulated Radiation Therapy (IMRT) -- advanced high precision RT that can conform to specific areas. Cost effective Analysis?

2. Are sites equipped with IMRT? If this is a positive study what implementation approaches are needed. If negative, will sites continue to use the technique due the cost benefit? Will the number of sites be adequate for the trials?

3. Should Patient Reported Outcomes be incorporated into this study?

4. What are the most effective ways to communicate risk/benefit to patients?

5. How accessible are RT facilities to patients that are participating in clinical trials

6. Are there biomarkers to identify patients at high risk of cognitive decline?
TAILORx: Results for Low Risk Patients

Prospective Validation of a 21-Gene Expression Assay in Breast Cancer


Results:  
IDFS: 93.8
DDFS: 99.0%
Community Enrollment: 18%

Prospective Study of MRI and Multiparameter Gene Expression Assay in DCIS
Genomics Driven Precision Medicine

- Underutilization of germline genetic testing among minorities
- Few studies have assessed views of patients about predictive and prognostic testing
- Patients confuse somatic testing with germline (e.g., familial risk, preventive options)
- Blacks have higher rates of concerns about psychological harms of genetic testing than Caucasians (48% vs. 20%), but no differences in willingness to participate in for predictive, prognostic, and pharmacogenetic testing  
  Gray, et al, JOP 2011

NCORP participates in genomics driven treatment and advanced imaging studies and is developing a genomic research agenda for symptom management.
Is the Network Equipped for a New Generation of Clinical Trials?

- Emphasis multiple agents
- Combination trials that are biomarker-based
- Biomarker development is primary
- Regulatory apparatus is adapted to modern biology
- Biobank for symptom science
# Enrollment to Treatment Precision Trials

## Accruals by Organization Type (Swim Lane)

<table>
<thead>
<tr>
<th>Swim Lane</th>
<th>A151216</th>
<th>% of A151216 pts</th>
<th>A081105</th>
<th>% of A081105 pts</th>
<th>E4512</th>
<th>% of E4512 pts</th>
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<tbody>
<tr>
<td>LAPS</td>
<td>77</td>
<td>19.49%</td>
<td>5</td>
<td>25%</td>
<td>1</td>
<td>14.29%</td>
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<tr>
<td>NCORP</td>
<td>170</td>
<td>43.04%</td>
<td>5</td>
<td>25%</td>
<td>4</td>
<td>57.14%</td>
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<tr>
<td>ROSTERED</td>
<td>148</td>
<td>37.47%</td>
<td>10</td>
<td>50%</td>
<td>2</td>
<td>28.57%</td>
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## Precision Medicine NCTN Trials: ALCHEMIST Accrual as of 9/18/15

<table>
<thead>
<tr>
<th>Swim Lane</th>
<th>Study</th>
<th>% of S1400 pts</th>
<th>sub-study</th>
<th>% of sub-study pts</th>
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<tr>
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<td>17.66%</td>
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<td>21.74%</td>
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<tr>
<td>NCORP</td>
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<td>40.05%</td>
<td>63</td>
<td>39.13%</td>
</tr>
<tr>
<td>ROSTERED</td>
<td>170</td>
<td>42.29%</td>
<td>63</td>
<td>38.13%</td>
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## Precision Medicine NCTN Trials: LungMAP Accrual as of 9/18/15
<table>
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<tr>
<th>Protocol #</th>
<th>Study Title</th>
<th>Activated</th>
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<tr>
<td>ACCL1033</td>
<td>A Comprehensive Approach to Improve Medication Adherence in Pediatric ALL</td>
<td>2/21/2012</td>
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<tr>
<td>ALTE11C1</td>
<td>Longitudinal Assessment of Ovarian Reserve in Adolescents with Lymphoma</td>
<td>6/17/2013</td>
</tr>
</tbody>
</table>
NCORP vs CCOP Accrual 2012 - 2014

- NCORP - 2014: 3661
- CCOP - 2013: 4648
- CCOP - 2012: 6307

Chart shows the comparison between NCORP and CCOP accruals for the years 2012 to 2014.
NCORP
2014 Minority and Non-Minority Accrual

M/U Cancer: CP/C 40%; Treatment: 50%
Community Sites: CP/C 16%; Treatment: 15%

MU NCORP
Minority: 271, 310
Non-Minority: 414, 315

NCORP
Minority: 474, 544
Non-Minority: 2486, 2971

Legend:
- CP/C
- Treatment
Other NCORP Trials

- Pragmatic -- more generalizable to post-trial patients
- Screening -- to provide evidence to current practices
- Post treatment Surveillance -- to provide evidence for in setting of significant variety in approaches
- Lifestyle -- diet and weight reduction on DFS
- National/ International Collaborations -- combined data analyses
- Overdiagnosis -- research agenda in development
- Financial Toxicities -- barrier for trials, quality of and access to care
Cancer Prevention Think Tank

• Current small portfolio of prevention trials
• Need to reinvigorate cancer prevention
• Think Tank Goals:
  • Review the current status of cancer prevention research
  • Identify research priorities in cancer prevention research to be conducted within NCORP
  • Identify 2-3 prevention trials
• Chair: Scott Lippman
NCORP Community Site, MU Community Site and Research Bases Geographic and Organizational Diversity

- Investigators (3,919)
- Components/Subcomponents (860)
- CCDR (394)

Community Sites (34)
- Distributed network (25)
- Integrated System (7)
- Small Network (2)

MU Community Sites (12)
- Academic (8)
- Non-Academic (4)

Research Bases (7)
- Research Bases
Academic/Community/NCI Partnership

- Heightened awareness of NCORP’s resource as a research infrastructure

- Clinical expertise is extensive and can facilitate the identification of health and cancer disparities

- Investigators provides direct input and feedback into the design and conduct of clinical trials
## NCORP Participation in NCI Initiatives

### 25 NCI Steering Committees Members
- Brain
- Breast
- CCDR
- Head & Neck
- Symptom Mgmt/QOL
- Thoracic
- Clinical Imaging
- GYN
- GI
- GU
- Leukemia
- Lymphoma
- Myeloma

### 22 Task Force Members
Clinical Trials & Translational Research Advisory Committee (CTAC)
NCI CIRBs
“NCORP is so massive, how does it all fit together?”

At the end of the day, it is the passion and commitment of the NCORP research team to provide quality cancer care to the patients in your communities....
Clinical Trials: Contributing Factors for Changes in Research Infrastructure

✓ Changes in the way cancer care is delivered
✓ Developments in the scientific environment
✓ Changes in community environment
✓ Changes in the relative commitment by NCI to cancer treatment, detection, and prevention

The world we created today has problems which cannot be solved by thinking the way we thought when we created them..... Albert Einstein
Delivery of Cancer Care Beyond Academic Centers

“We created the specialty of medical oncology and it grew like wildfire. You suddenly have..2,800 physicians who are young and well-trained.. Who are going to, one way or another, treat this population of patients. They might as well be part of the research effort.” Vince DeVita, NCI, 1981

“Existing mechanisms for providing service at the community level should be extended, rather than have NCI set up a new, and possibly competitive, program at a time of reduced funding....Although high quality clinical research is expected from this program, the level of care might not compare to that given at centers. Community Clinical Oncology Program (CCOP): 1983 Minority-Based CCOPs: 1990
Thank you!
Cancer Disparities Initiatives

- Clinical Trials
  - Trans Research Base Committees
  - AACR, ASCO, ACS, NCI Position Paper
  - NCORP Clinical Trials Log
  - Steering Committee M/U representation & disparities research expertise

- Cancer Care Delivery Research
  - Focus on the role of organizations in reducing disparities
  - Utilization of resources from the Center to Reduce Cancer Health Disparities’
  - Evaluating financial toxicities in cancer care
A lot has happened “behind the scenes”
Vision for Transformation of System for NCI Late-Phase Tx/Imaging Trials - 2014 and Beyond

- Launch trials rapidly & complete accrual per defined guidelines through integrated national network sites

- Promote user-friendly, harmonized processes to extramural community (investigators, patients, advocates, & industry) & facilitate collaborations with partners

- Provide common infrastructure to perform large scale testing of increasingly smaller subsets of molecularly-defined cancers (Examples: LUNG-Map, ALCHEMIST, MATCH)

- Focus on research questions not well supported in a commercial environment
# Behind the Scenes

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<tr>
<th>Resources</th>
<th>Infrastructure/Regulatory</th>
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<tr>
<td>✓ NCORP Portal</td>
<td>✓ Systems Intergration</td>
</tr>
<tr>
<td>✓ Public Website</td>
<td>✓ Central IRB</td>
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<tr>
<td>✓ Interactive Map</td>
<td>✓ Trial Stopping Rules</td>
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<tr>
<td>✓ Guidelines Update</td>
<td>✓ Cancer Control Biobanks</td>
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<td>✓ Webinars</td>
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