NCI Community Oncology Research Program
Accrual Analysis
August 2014-July 2018

Clinical Trials and Translational Research Advisory Committee
November 7, 2018

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Chief, Community Oncology and Prevention Trials Research Group
Division of Cancer Prevention
NCORP Accrual Analysis

- NCORP Structure to Support Accrual
- Accrual by Research Type
- Characteristics of NCORP Patients/Participants
- Concept/Protocol Timelines
NCORP Research Portfolio

- Cancer Control, Prevention, Screening, Post-Treatment Surveillance
- Quality of Life Embedded in Treatment Trials
- Cancer Care Delivery
- Advanced Imaging and Treatment Trials
Sources of NCORP Trials/Studies: Research Bases

- University of Rochester
- COG (Pediatric)
- ECOG-ACRIN
- Alliance
- Wake Forest
- NRG Oncology

National Clinical Trials Network (NCTN) Group & NCORP Research Base
NCORP Academic Research Bases
Sources of NCORP Academic/Community Partnership

- Research Base Concepts
- Federal Funding e.g., RPG Pool DOD
- Non-Federal Funding e.g., PCORI, ACS, Lymphoma Society

NCORP Research Bases

NCORP Community and Minority/Underserved Investigators
NCORP Community Site, M/U Community Site and Research Bases Geographic and Organizational Diversity

- Investigators (4,061)
- Components/Subcomponents (960)

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

Updated: September 2018
## Average Number of Trials Available per Year

<table>
<thead>
<tr>
<th>Year</th>
<th>Trials Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>46</td>
</tr>
<tr>
<td>2015</td>
<td>43</td>
</tr>
<tr>
<td>2016</td>
<td>44</td>
</tr>
<tr>
<td>2017</td>
<td>46</td>
</tr>
<tr>
<td>2018</td>
<td>48</td>
</tr>
</tbody>
</table>
NCORP Cancer Control/Prevention Accrual by Year:
8/1/14 – 7/31/18

<table>
<thead>
<tr>
<th>Year</th>
<th>CP/C</th>
<th>TREATMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>2399</td>
<td>3583</td>
</tr>
<tr>
<td>2015</td>
<td>2725</td>
<td>3130</td>
</tr>
<tr>
<td>2016</td>
<td>2596</td>
<td>3430</td>
</tr>
<tr>
<td>2017</td>
<td>3752</td>
<td>3118</td>
</tr>
</tbody>
</table>

Total: 24,733
NCORP Cancer Control/Prevention Accrual
2014 - 2017

ALL NCORP: 11456
NCORP - Community: 13261
NCORP MU Community: 10152
NCORP Cancer Control/Prevention: 10746
CP/C: 1304
Treatment: 2515
NCORP Cancer Care Delivery Research Studies

• Cancer Care Delivery Research is a multidisciplinary science that seeks to improve clinical outcomes and patients well-being by intervening on patient, clinician, and organizational factors that influence care delivery

• CCDR Studies may include:
  – Patients
  – Caregivers
  – Non-patient participants (clinicians, physicians, pharmacists)
  – Practices/Organizations
NCORP ACCRUAL
2014 - 2017

CP/C: 11,472
TX: 13,261
QOL: 3,705
CCDR: 2,838
Total: 31,276
NON-NCORP* ACCRUAL TO CP/C & QOL TRIALS
2014 - 2017

*Non-NCORP: LAPs, Affiliates, Rostered
NCI Tissue Procurement Studies

Patient Derived Model

100 Blood specimens
Columbia NCORP
Delaware/Christiana NCORP
Heartland NCORP
Michigan NCORP
Nevada NCORP
Northwest NCORP
Ozark NCORP
Stroger NCORP
West Michigan NCORP

Blood and Tissue Pairs (1st supplement)
Heartland NCORP (29)
Ozarks NCORP (28 + 8 blood only)

Blood and Tissue Pairs (2nd supplement)
Ozark NCORP (36 + 3 blood only)
Michigan NCORP (30)
West Michigan NCORP (30)
Wichita NCORP (30)

Early Onset Malignancy Initiative

To sequence early age malignancies in 6 cancers among 4 racial/ethnic groups, M/U Sites: 82
NCORP Accrual to Precision Medicine Trials

### ALCHEMIST Accruals by Organization

<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>
<th>EAS142</th>
<th>% of EAS142 pts</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCORP</td>
<td>1329</td>
<td>35.34%</td>
<td>75</td>
<td>32.33%</td>
<td>26</td>
<td>36.11%</td>
<td>211</td>
<td>40.34%</td>
</tr>
</tbody>
</table>

### LungMap Accruals by Organization

<table>
<thead>
<tr>
<th>Study</th>
<th>% of $1400 pts</th>
<th>sub-study</th>
<th>% of sub-study pts</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCORP</td>
<td>640</td>
<td>230</td>
<td>35.11%</td>
</tr>
</tbody>
</table>

### NCI Community Oncology Research Program

**Molecular Analysis for Therapy Choice (MATCH)**

44 Percent (2788/6408) of Patients Registered for Screening in the NCI MATCH Trial are from NCORP Community and Minority Community Sites
NCORP Accrual - 2014-2017
An Academic/Community Partnership

Cancer control, prevention, screening
11,456 patients

NCTN) treatment and imaging trials
13,261 patients

Quality of Life
3,705 patients

Cancer Care Delivery Research
2838 patients and clinicians

Tissue Acquisition Studies
276 patients
NCORP SCREENING ACCRUAL
2014 - 2017

- 2014: 594
- 2015: 1723
- 2016: 3453
- 2017: 1848
NCORP Overall Minority Enrollment 2017

- Minority: 24.0%
- Non-Minority: 74.3%
- Not Reported: 0.8%
- Unknown: 0.9%
Minority Enrollment by Community Type

Community Site NCORPS
Minority and Non-Minority Enrollment

<table>
<thead>
<tr>
<th>Category</th>
<th>Minority</th>
<th>Non-Minority</th>
<th>Unknown</th>
<th>Not Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>18.0%</td>
<td>80.0%</td>
<td>1.0%</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

Minority/Underserved NCORPS
Minority and Non-Minority Enrollment

<table>
<thead>
<tr>
<th>Category</th>
<th>Minority</th>
<th>Non-Minority</th>
<th>Unknown</th>
<th>Not Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>54.0%</td>
<td>44.0%</td>
<td>1.0%</td>
<td>1.0%</td>
</tr>
<tr>
<td>Racial Categories</td>
<td>Not Hispanic or Latino</td>
<td>Hispanic or Latino</td>
<td>Unknown/Not Reported Ethnicity</td>
<td>TOTAL</td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>------------------------</td>
<td>-------------------</td>
<td>--------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>135</td>
<td>18</td>
<td>8</td>
<td>161</td>
</tr>
<tr>
<td>Asian</td>
<td>681</td>
<td>16</td>
<td>13</td>
<td>710</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>96</td>
<td>6</td>
<td>1</td>
<td>103</td>
</tr>
<tr>
<td>Black or African American</td>
<td>2,325</td>
<td>51</td>
<td>119</td>
<td>2,495</td>
</tr>
<tr>
<td>White</td>
<td>17,787</td>
<td>1,273</td>
<td>863</td>
<td>19,923</td>
</tr>
<tr>
<td>More than One Race</td>
<td>94</td>
<td>20</td>
<td>405</td>
<td>519</td>
</tr>
<tr>
<td>TOTAL (All Reported Racial Categories)</td>
<td>21,118</td>
<td>1,384</td>
<td>1,407</td>
<td>23,911</td>
</tr>
</tbody>
</table>

| Unknown or Not Reported               | 200                    | 371               | 251                            | 822   | 3.4% of All Pts Enrolled with Unknown/Not Reported Race |
| TOTAL                                 | 21,318                 | 1,755             | 1,658                          | 24,733|                                   |
DCP-001: Screening Tool
10,772 Entries, 8,744 consented to DCP-001

Enrolled on a Clinical Trial: 6193/8744 (71%)
Reasons for Not Enrolling on a Clinical Trial

2,551/8744

- Patient did not meet trial eligibility criteria: 554 (50%)
- Patient was eligible but declined participation: 736
- Patient was eligible but MD declined to offer participation: 847 (47%)
- Patient was eligible but study suspended: 24, 11, 8, 13
Patient Income

- Less than $25,000: 986 (17%)
- $25,000 to $50,000: 1260 (21%)
- $51,000 to $100,000: 1522 (25%)
- More than $100,000: 1132 (19%)
- Patient refused: 1071 (18%)
Patient Education

- **No formal education**: 5 (0.1%)
- **Grade School**: 69 (1.2%)
- **Not high school graduate**: 266 (4%)
- **High school graduate (including equivalency)**: 1390 (23%)
- **Some college or associate degree**: 1866 (31%)
- **Bachelor's Degree**: 1303 (22%)
- **Master's Degree**: 667 (11%)
- **Graduate or professional degree**: 178 (3%)
- **Doctoral degree or professional degree**: 188 (3%)
- **Blank**: 39 (0.7%)
Changes to NCORP Concept & Protocol
Target Timeline Goals (Effective 8/1/2018)

Target Timeline Goals:

1. Concept Receipt to Approval 120 days
2. Protocol Authoring 90 days
3. Protocol Review & Approval 175 days
4. Protocol Approval to Activation 90 days

Total Target Timeline Goal 475 days
**NCORP Target and Absolute Goals**

<table>
<thead>
<tr>
<th>Concept Receipt to Protocol Activation</th>
<th>Protocol Receipt to Protocol Activation (Studies without Concepts)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Target</strong></td>
<td><strong>Absolute</strong>*</td>
</tr>
<tr>
<td>475 days</td>
<td>525 days</td>
</tr>
</tbody>
</table>

*Absolute Goal = includes one additional revision cycle 50 days (Consensus Review Letter to Revision Receipt 30 days + Revision Receipt to Approval On-hold 20 days)*
### Trials Activated & Completed During NCORP through 7/30/2018

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Title</th>
<th>Activation date</th>
<th>Accrual Cut Off Date</th>
<th>Planned Accrual</th>
<th>Actual Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>A221303</td>
<td>Randomized Study of Early Palliative Care Integrated with Standard Oncology Care Versus Standard Oncology Care Alone in Patients with Incurable Lung or Non-Colorectal Gastrointestinal Malignancies</td>
<td>5/15/2015</td>
<td>4/10/2017</td>
<td>400</td>
<td>405</td>
</tr>
<tr>
<td>EA1141</td>
<td>Comparison of Abbreviated Breast MRI and Digital Breast Tomosynthesis in Breast Cancer Screening in Women with Dense Breasts</td>
<td>9/2/2016</td>
<td>11/7/2017</td>
<td>1450</td>
<td>1516</td>
</tr>
<tr>
<td>E4112</td>
<td>Prospective Study of Magnetic Resonance Imaging (MRI) and Multiparameter Gene Expression Assay in Ductal Carcinoma In Situ (DCIS)</td>
<td>2/17/2015</td>
<td>4/28/2016</td>
<td>350</td>
<td>368</td>
</tr>
<tr>
<td>NRG-CC001</td>
<td>A Randomized Phase III Trial of Memantine and Whole-Brain Radiotherapy With or Without Hippocampal Avoidance in Patients With Brain Metastases</td>
<td>7/13/2015</td>
<td>3/12/2018</td>
<td>510</td>
<td>513</td>
</tr>
<tr>
<td>NRG-CC002</td>
<td>Pre-Operative Assessment and Post-Operative Outcomes of Elderly Women with Gynecologic Cancers</td>
<td>2/10/2015</td>
<td>11/2/2015</td>
<td>228</td>
<td>190</td>
</tr>
<tr>
<td>URCC-13070</td>
<td>Improving Communication for Cancer Treatment: Addressing Concerns of Older Cancer Patients and Caregivers</td>
<td>10/29/2014</td>
<td>4/30/2017</td>
<td>1056</td>
<td>973</td>
</tr>
<tr>
<td>URCC-13091</td>
<td>Feasibility of Omega-3 Supplementation for Cancer-Related Fatigue</td>
<td>2/26/2015</td>
<td>3/31/2016</td>
<td>75</td>
<td>108</td>
</tr>
<tr>
<td>URCC-14079</td>
<td>Effectiveness of Prophylactic Topical Agents for Radiation Dermatitis</td>
<td>10/13/2015</td>
<td>6/30/2016</td>
<td>180</td>
<td>192</td>
</tr>
</tbody>
</table>
Thank you!