NCI National Cancer Trial Network (NCTN) Program Overview

Jessica Huamani-Bundy, MS, CCRC
Clinical Research Manager, Sr.
Winship Cancer Institute & Department of Radiation Oncology
The overall goal of the NCI’s National Clinical Trials Network (NCTN) Program is to conduct definitive, randomized, late phase clinical treatment trials and advanced imaging trials across a broad range of diseases and diverse patient populations.

The NCTN program launched March 3rd, 2014.
An Open Network

• Member institutions of Network Groups will be able to enroll patients on all adult phase 3 trials as well as select early phase trials, irrespective of the specific Network Group that is leading the trial.

• In addition, select trials for adolescent and young adults will be open to all member institutions/sites.
Funded Network Groups

- Alliance
- SWOG
- ECOG-ACRIN (Formerly ECOG & ACRIN)
- NRG Oncology (Formerly NSABP, RTOG, & GOG)

At Emory University/Winship Cancer Institute, we will credit enrollment to ECOG-ACRIN or NRG
Participation Category

The U10 grant application was approved early 2014, Winship Cancer Institute was awarded the role of:

Lead Academic Participating Site (LAPS)

This translates into a higher reimbursement per case enrollment. Payment is procured via the grant award.
Emory Study Sites

- LAPS Main Members:
  - Emory University/Winship Cancer Institute - GA005
  - Emory University Midtown – GA013
  - Emory Saint Joseph’s Hospital – GA011

- LAPS Affiliates:
  - Grady Health System - GA003
  - Atlanta VA Medical Center - GA002
What will be expected?

• LAPS Main Members:
  Minimum of 80 patients accrued from three sites

• LAPS Affiliates:
  Minimum of 20 patients accrued from the two participating sites
All NCTN trials, including active legacy trials (defined as trials open prior to the start of the NCTN), will use OPEN for enrollments.

OPEN roles pre-NCTN will be retained if the institution is an active participant in the NCTN.

OPEN will be used to document requirements for additional reimbursements for correlative, QOL and supplemental funds, when required.
Site users must have all the following to access OPEN:

- Active CTEP-IAM account
- Active or follow-up treatment roster status on a Network Group roster
- Active Registrar role on a Network Group roster
Medidata RAVE

• All new trials in the NCTN will be using Rave (clinical data management system) for data collection.
• Active legacy trials will continue to use the data collection mechanism used prior to the NCTN.
• Current Rave roles will be carried over to the NCTN as long as the affiliated site retains an active Network Group affiliation.
How sites get paid

- The NCTN will follow per case management principles for reimbursement for CTEP treatment and advanced imaging trials.
- Funding for trial activities will fall under one of the following categories:
  - Screening for Intervention
  - Basic Intervention
  - Advanced Imaging
  - Biospecimen Collection
  - Special (complex or rare disease trials)
  - Quality of Life
  - Non-NCI/DCTD Funding (e.g., Industry)
How sites get paid (Cont)

**PROTOCOL E1609**

A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interferon Alpha-2b for Resected High-Risk Melanoma

*Study Activation: 5/25/2011*

<table>
<thead>
<tr>
<th>Funding Source and Study Component</th>
<th>Mandatory/ Mandatory Request or Event/ Optional</th>
<th>Study Specific Notes</th>
<th>Enter Date in OPEN?</th>
<th>NCTN Funding Amount per Patient (a) Standard/ LAPS</th>
<th>NCORP Credit per Patient (b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal Base Intervention (Standard/ High Performance (HP) LAPS &amp; NCORP)</td>
<td>Mandatory</td>
<td></td>
<td>No</td>
<td>$2250 / $4000</td>
<td>1.0 / 1.6 (Tx)</td>
</tr>
<tr>
<td>Federal Biospecimen – slides</td>
<td>Mandatory Request</td>
<td>1</td>
<td>Yes</td>
<td>$200</td>
<td>.08 (Tx)</td>
</tr>
<tr>
<td>Federal Biospecimen – serum</td>
<td>Optional</td>
<td>1</td>
<td>Yes</td>
<td>$100</td>
<td>.04 (Tx)</td>
</tr>
<tr>
<td>Federal Biospecimen – whole blood</td>
<td>Optional</td>
<td>1</td>
<td>Yes</td>
<td>$100</td>
<td>.04 (Tx)</td>
</tr>
<tr>
<td>Federal Biospecimen – peripheral blood</td>
<td>Optional</td>
<td>1</td>
<td>Yes</td>
<td>$100</td>
<td>.04 (Tx)</td>
</tr>
<tr>
<td>Federal Quality of life</td>
<td>Optional</td>
<td>2</td>
<td>Yes</td>
<td>$1000</td>
<td>.40 (CC)</td>
</tr>
</tbody>
</table>

**Total Potential Federal Funds or NCORP credits (Standard/HP) (e)**

$3750 / $5500 (c)

**Non-Federal**

| Industry funds | Mandatory | No | $425 | $425 |

**Total Potential Non-Federal Funds (d)**

$425 (b)

**Total Potential Funds (e)**

$4175 / $5925 (c)
OPEN Funding Update

• For LAPS to track the per case funding for specific tests and/or biospecimen submission, CRCs are required to enter completion dates in the OPEN “funding module” post-enrollment.

• Completion dates for biospecimens will be the day the sample was sent out to the sponsor.
OPEN Funding Screen

- To enter the data needed to trigger funding in a trial, click the history tab & search for the Patient ID (PID) associated with the enrollment.
- Enrollments with additional funding will have a ‘$’ icon next to the protocol number.
- Click on ‘select’ next to the patient enrollment with the required PID.
- The summary screen will be displayed.
• Click on the funding tab, and the enrollment data will be displayed at the top and a funding table will be populated with each of the funding types available.
• Enter the date MM/DD/YYYY when the test was completed and save.

Completion Date is Required for reimbursement
Timely entry of dates in OPEN is recommended as this will record completion for per case funding and tracking.

CRCs please ship your study specimens for the ECOG-ACRIN and NRG Oncology Trials within a week of collection and as per protocol specifications.
# LAPS Accrual Summary

LAPS Accrual 03/01/2014-09/30/2014

<table>
<thead>
<tr>
<th></th>
<th>LAPS Main Member</th>
<th>LAPS Affiliates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emory:</td>
<td>21</td>
<td>8</td>
</tr>
<tr>
<td>Midt’n:</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>ESJH</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Grady</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>VAMC:</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>NRG Oncology</td>
<td>28</td>
<td>9</td>
</tr>
<tr>
<td>ECOG-ACRIN</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>49</td>
<td>16</td>
</tr>
</tbody>
</table>

Summary March-September 2014

<table>
<thead>
<tr>
<th></th>
<th>LAPS Main Member</th>
<th>LAPS Affiliate</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAPS Main Member</td>
<td>66</td>
<td>25</td>
</tr>
<tr>
<td>LAPS Affiliates</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>91</td>
<td></td>
</tr>
</tbody>
</table>
Items to Note

• Records from OPEN enrollment and specimen funding tracking will be reported monthly to the Cooperative Group Committee Meeting.

• CRCs please ensure you continue to update ONCORE after you have registered a patient to ECOG-ACRIN or NRG Oncology.

• Your cooperation is greatly appreciated