The NCI National Clinical Trials Network (NCTN)
Changes in Rosters, Roles, OPEN and Rave after NCTN
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Darlene Kiniry, NRG Oncology

NRG Oncology Semi Annual Meeting
Chicago, IL
11 Jul 2014
Agenda

- Overview
- Network Group Organization Structure
- Participation Categories
- Crediting Rules
- OPEN
- Rave
- Person Roles
- NCTN Studies
- CTSU Website
- CIRB
- Per Case Management Funding
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.
NCTN Overview (2)

• The NCTN was launched on March 3, 2014.

• The Network now consists of:
  − 4 Adult U.S. Network Groups
  − 1 Pediatric U.S. Network Group
  − 1 Canadian Network Group

• LAPS – Lead Academic Participating Site
  − Separate grants.
  − Academic institutions that provide scientific leadership in the development and conduct of clinical trials as well as substantial accrual to clinical trials conducted across the entire Network.
Network Group Structure

NCTN Group

Tier 1
- LAPS (grantee) (org type = LAPS)
- Main Member (acquiring) (org type = institution)
- Main Member (non-acquiring / administrative) (org type = network)
- CCOP (grantee) (org type = CCOP)
- NCORP (grantee) (org type = NCORP)
- NCORP MU (grantee) (org type = NCORP)

Tier 2
- LAPS affiliate (LAPS A)
- LAPS main member (LAPS MM)
- LAPS integrated component (LAPS IC)
- LAPS aligned affiliate (LAPS AA)
- Affiliate
- Affiliate
- CCOP component
- NCORP component (NCORP C)
- NCORP MU component (NCORP MU C)

Tier 3
- LAPS sub affiliate (LAPS SA)
- LAPS aligned sub affiliate (LAPS ASA)
- Sub affiliate
- Sub affiliate
- Sub affiliate
- CCOP sub component (CCOP SC)
- NCORP sub component (NCORP SC)
- NCORP MU sub component (NCORP MU SC)

Legend:
- LAPS Package
- Rostered
- CCOP Package

Notes:
1. Pre-approval for Main Member (non-acquiring / administrative) code required from CTEP
2. Attribute for MB CCOP provided by DCP and viewable in RSS
3. Attribute for PEDS ONLY provided by DCP and viewable in RSS
Participation Categories

Sites are able to participate in one of 3 mutually exclusive ways with the exception of some pediatric sites. Sites may be members of multiple Network Groups with varying types of membership but the NCTN component must remain the same across all Groups.

<table>
<thead>
<tr>
<th>NCTN Component</th>
<th>Component Tiers/Membership</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead Academic Participating Sites (LAPS)</td>
<td>• LAPS Main Member&lt;br&gt;• LAPS Integral Component&lt;br&gt;• LAPS Affiliates/Sub-Affiliates&lt;br&gt;• LAPS Aligned Affiliates/Sub Affiliates (funded by Network Group)</td>
</tr>
<tr>
<td>CCOPs/MB-CCOPs (NCORPs/NCORP MUs)</td>
<td>• CCOP/NCORP Component&lt;br&gt;• CCOP/NCORP Sub-Component</td>
</tr>
<tr>
<td>Adult Network Group OR</td>
<td>• Main Member&lt;br&gt;• Affiliate&lt;br&gt;• Sub-Affiliate</td>
</tr>
<tr>
<td>Pediatric Network Group</td>
<td>• Main Member</td>
</tr>
</tbody>
</table>
Crediting Rules

• US sites may credit any participating Network Group to which the site and credited investigator are affiliated and participating on the protocol.

• Canadian sites must credit the NCTN Group that holds the CTA.

• International sites must credit the Lead Protocol Organization (LPO) if they are a member of the LPO.

• International sites that are not members of the LPO must receive approval from their credited Group and consistently credit the same Group for the protocol.
Oncology Patient Enrollment Network (OPEN)

- All NCTN trials, including active legacy trials (defined as trials open prior to the start of the NCTN), use OPEN for enrollment.

- Pre-NCTN OPEN roles were 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.
OPEN Access

Site users must have **all** the following to access OPEN:

- Active CTEP-IAM account
- Active treatment roster status on a Network Group roster
- Active Registrar role on a Network Group roster

 نقطه: CTSU Roster no longer controls access
All new trials in the NCTN will be using Rave for data collection.

Active legacy trials continue to use the data collection mechanism used prior to the NCTN.

Pre-NCTN Rave roles were retained if the institution is an active participant in the NCTN.
Rave Access

Site users must have all of the following to access Rave:

- Active CTEP-IAM account

- Active or follow-up treatment roster status on a Network Group roster

- Active Rave role on a Network Group roster

- CTSU Roster no longer controls access
Rave Access

• A number of users may have received additional Rave Invitations for studies as access rights now look across organizations.

• Invitations may be managed by taking one of the following actions:
  − Accept the invitation in iMedidata.
  − Decline the invitation in iMedidata (this action is not recommended if access may be needed in the future as manual intervention will be needed to regain access).
  − Ignore the invitation until access need is determined.
  − Adjust Rave roles in the roster by withdrawing the institutional Rave roles from persons at the site and reassigning the Rave roles to each person at the protocol level.
Access Paradigm

- **OLD (Pre NCTN)**
  - For **OPEN and Rave**, access was controlled by the LPO roster for sites that were members of the LPO and by the CTSU roster for cross-group participants.

- **CTSU Website**: All persons that were members of the CTSU could view protocol documents for the Cooperative Group studies.

- **NEW (NCTN)**
  - For **OPEN and Rave**, the LPO and Participating Organization (PO) rosters control access.

- **CTSU Website**: All Persons must be members of a LPO or PO roster to view the protocol documents.
Person Roster Rules

• All persons must have a CTEP ID assigned through the Investigator Registration Process for MDs and DOs or CTEP-IAM for associates.

• All Persons must re-register with CTEP annually to maintain their roster status.

• Persons must be linked to a clinical site or administrative organization.

• Access to protocols, OPEN, and Rave is controlled by the LPO and Participating Organization (PO) rosters.
# Adding Persons and Roles

<table>
<thead>
<tr>
<th>Event</th>
<th>Type of Site</th>
<th>System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add Person</td>
<td>CCOP/NCORP</td>
<td>CCOPSYS</td>
</tr>
<tr>
<td>Withdraw Person</td>
<td>CCOP/NCORP</td>
<td>CCOPSYS</td>
</tr>
<tr>
<td>Add Person</td>
<td>LAPS</td>
<td>Contact Group**</td>
</tr>
<tr>
<td>Withdraw Person</td>
<td>LAPS</td>
<td>Contact Group**</td>
</tr>
<tr>
<td>Add Person</td>
<td>Rostered Site (MM/Affiliates)</td>
<td>Contact Group**</td>
</tr>
<tr>
<td>Withdraw Person</td>
<td>Rostered Site</td>
<td>Contact Group**</td>
</tr>
<tr>
<td>Add Primary Role*</td>
<td>All</td>
<td>Contact Group**</td>
</tr>
<tr>
<td>Add Non-Primary Role</td>
<td>All</td>
<td>Site Roles (CTSU website)</td>
</tr>
</tbody>
</table>

* Primary roles are defined as those that cannot be added through Site Roles

** By Fall 2014, this can be done via CTSU Website using the Roster Update Management System (RUMS)
Standard Roles

<table>
<thead>
<tr>
<th>System</th>
<th>Role for all Rosters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rave</td>
<td>Rave CRA, Read Only, Site Investigator, CRA (LabAdmin), SLA</td>
</tr>
<tr>
<td>OPEN</td>
<td>Registrar</td>
</tr>
<tr>
<td>TRIAD</td>
<td>Site User (maintained on the CTSU roster)</td>
</tr>
</tbody>
</table>

- Select roles can be maintained from the Site Roles tab for all NCTN groups.
- Rules for roles maintenance vary by NCTN Group.
- For NRG, the Lead RA, Co-Lead RA, and Local Lead RA can add roles.
- Resources on the Site Roles tab include a Roles & Access table and updated Help document.
Managing Site Roles

<table>
<thead>
<tr>
<th>WA</th>
<th>CTEP ID</th>
<th>Name</th>
<th>CTEP Reg. Dt.</th>
<th>Action</th>
<th>Site</th>
<th>Role</th>
<th>Protocol/Role</th>
<th>Effective Date</th>
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<tbody>
<tr>
<td>A51305</td>
<td>Ageton, Cheryl</td>
<td>11/18/2014</td>
<td>Action</td>
<td>SD021</td>
<td>Rave CRA, Lead RA, Registrar</td>
<td></td>
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<tr>
<td>A52787</td>
<td>Andersen, Emily</td>
<td>10/10/2013</td>
<td>Action</td>
<td>SD021</td>
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<tr>
<td>I51197</td>
<td>Baker, Scott L.</td>
<td>08/23/2014</td>
<td>Action</td>
<td>SD021</td>
<td>Rave CRA, Lead RA, Registrar</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>A52536</td>
<td>Bertram, Michaela Sue</td>
<td>06/02/2015</td>
<td>Action</td>
<td>SD021</td>
<td>Rave CRA, Lead RA, Registrar</td>
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<td></td>
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<tr>
<td>A50400</td>
<td>Binder, Janna</td>
<td>01/23/2015</td>
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<tr>
<td>A52269</td>
<td>Bohlen, Krista N.</td>
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<td>A54092</td>
<td>Cyr, Brigitte</td>
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<td>I28147</td>
<td>Dosch, Wade Edward</td>
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</tbody>
</table>

New Role: Enter role details and click 'Add Role'

- Name: Bertram, Michaela Sue
- CTEP IAM ID: 525369
- Group: NRG
- Parent Site: SD021

Select Role:
- Contact/Grants
- Fiscal Contact
- Local PI
- Rave CRA
- Read Only
- Registrar
- Site Investigator
## NRG Roster Rules (1)

<table>
<thead>
<tr>
<th>Sites</th>
<th>Roles</th>
<th>Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAPS and CCOP (Tier 1)</td>
<td>Lead RA</td>
<td>Site Roles Application</td>
</tr>
<tr>
<td></td>
<td>Co-Lead RA</td>
<td>Site Roles Application</td>
</tr>
<tr>
<td></td>
<td>LAPS PI</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Check Addressee</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fiscal Contact</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Grants Contact</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PI</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Contact PI</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Local PI</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rave CRA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Read Only</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Registrar</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Site Investigator</td>
<td></td>
</tr>
<tr>
<td>LAPS and CCOP (Ties 2 and Tier 3)</td>
<td>Local Lead RA</td>
<td>Site Roles Application</td>
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<tr>
<td></td>
<td>Local PI</td>
<td>RAVE</td>
</tr>
<tr>
<td></td>
<td>Rave CRA</td>
<td>RAVE</td>
</tr>
<tr>
<td></td>
<td>Read Only</td>
<td>OPEN</td>
</tr>
<tr>
<td></td>
<td>Registrar</td>
<td>RAVE</td>
</tr>
<tr>
<td></td>
<td>Site Investigator</td>
<td>RAVE</td>
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</table>
## NRG Roster Rules (2)

<table>
<thead>
<tr>
<th>Sites</th>
<th>Roles</th>
<th>Access</th>
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</thead>
<tbody>
<tr>
<td><strong>Main Members</strong></td>
<td>Lead RA</td>
<td>Site Roles Application</td>
</tr>
<tr>
<td></td>
<td>Co-Lead RA</td>
<td>Site Roles Application</td>
</tr>
<tr>
<td></td>
<td>Check Addressee</td>
<td>RAVE</td>
</tr>
<tr>
<td></td>
<td>Fiscal Contact, Grants Contact</td>
<td>RAVE</td>
</tr>
<tr>
<td></td>
<td>PI, Contact PI</td>
<td>OPEN</td>
</tr>
<tr>
<td></td>
<td>Rave CRA</td>
<td>RAVE</td>
</tr>
<tr>
<td></td>
<td>Read Only</td>
<td>OPEN</td>
</tr>
<tr>
<td></td>
<td>Registrar</td>
<td>RAVE</td>
</tr>
<tr>
<td></td>
<td>Site Investigator</td>
<td></td>
</tr>
<tr>
<td><strong>Affiliates and Sub-affiliates</strong></td>
<td>Local Lead RA</td>
<td>Site Roles Application</td>
</tr>
<tr>
<td></td>
<td>Local PI</td>
<td>RAVE</td>
</tr>
<tr>
<td></td>
<td>RAVE CRA</td>
<td>RAVE</td>
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<tr>
<td></td>
<td>Read Only</td>
<td>OPEN</td>
</tr>
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<td>Registrar</td>
<td>RAVE</td>
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<tr>
<td></td>
<td>Site Investigator</td>
<td></td>
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<tr>
<td><strong>Main Member Follow Up Only</strong></td>
<td>Lead RA</td>
<td>Site Roles Application</td>
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<tr>
<td></td>
<td>PI, Contact PI</td>
<td>RAVE</td>
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<td></td>
<td>Fiscal Contact</td>
<td>RAVE</td>
</tr>
<tr>
<td></td>
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<td>RAVE</td>
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<tr>
<td></td>
<td>READ Only</td>
<td>RAVE</td>
</tr>
<tr>
<td></td>
<td>Site Investigator</td>
<td></td>
</tr>
</tbody>
</table>
Studies Available in the Network

- All phase 3 studies.
- All phase 2/3 studies.
- All phase 2 for which CTEP holds the IND.
- Selected other phase 2 studies with CTEP approval.
- Selected AYA studies with CTEP approval.
- Other Networks’ studies may be available with CTEP approval.
CTSU Website New Protocol Screens

• Home Tab - a quick glance of protocol basics, including protocol status, accrual information, participation information and more.

• Funding Information Tab - contains all funding associated with a protocol (for all NCTN protocols).

• LPO Documents Tab - contains the protocol and all associated documentation, (formerly named “documents”).

• Drug Safety Notifications Tab - contains all DSNs for drugs associated with the protocol.
Protocol Screens (2)

NRG-HN001
Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA)

Protocol Status: ACTIVE (Protocol Status Date: 04/21/2014)
Activation Date: 04/21/2014
Lead Organization: NRG
Phase: II/III
CIRB Approved: Yes Canadian Sites: Protocol Not Available
Accrual: Target: 758
Total: 0 (In OPEN: 0 )
As of: 06/19/14

Participation: Participation Information

<table>
<thead>
<tr>
<th>#</th>
<th>Org Type</th>
<th>Participant</th>
<th>Role Type</th>
<th>Participation Type</th>
<th>Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NCTN</td>
<td>SWOG</td>
<td>ALL</td>
<td>CROSS-NETWORK</td>
<td>04/22/2014</td>
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<tr>
<td>2</td>
<td>NCTN</td>
<td>ECOG-ACRIN</td>
<td>ALL</td>
<td>CROSS-NETWORK</td>
<td>04/22/2014</td>
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<tr>
<td>3</td>
<td>NCTN</td>
<td>ALLIANCE</td>
<td>ALL</td>
<td>CROSS-NETWORK</td>
<td>04/22/2014</td>
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<tr>
<td>4</td>
<td>NCTN</td>
<td>NRG</td>
<td>ALL</td>
<td>LEAD</td>
<td>02/26/2014</td>
</tr>
</tbody>
</table>

NRG-HN001 will be using the OPEN Registration System beginning 04/21/2014. To learn more about how OPEN works please view the Training and Demonstration materials located on the OPEN tab of the CTSU members’ website or through the OPEN URL at https://open.ctsu.org.

Rave
NRG-HN001 utilizes Medidata Rave for data collection and submission. Authorized users can use the RAVE application to enter the clinical data for this protocol.
NCI Central Institutional Review Board (CIRB)

- All U.S. Institutions/Sites participating in NCTN trials as a member of one or more Network Groups will be required to use the NCI CIRB as the IRB of record in the future.
  - More information on timelines for joining the CIRB and the waiver process will be released later this year.

- A waiver will only be granted if it can be demonstrated that an institution’s local IRB is able to review studies in a similar time-frame.
  - The waiver process for a site to be exempt from using the CIRB will be established in late 2014.
NCI CIRB Independent Model
Sites

• In June CTSU has started receiving the CIRB approvals electronically from CIRB.
• Starting soon institutions utilizing the CIRB will no longer be required to send documentation of initial, continuing and amendment reviews to the CTSU.
• The CTSU is able to process an institution’s CIRB approvals by:
  – Verifying the institution is on the CIRB’s roster in RSS.
  – Using a new CTSU Site Preference feature on the CTSU website to record which CIRB Institutions are participating in a CIRB approved trial (Phase 2 of the implementation).
• Information on the transition was released in the CTSU BI-monthly broadcasts in June and July.
• Educational material is now available on the CTSU webpage
Per Case Management Funding

- The NCTN trials will follow NCI’s CTEP per case management funding principles for cancer treatment and advanced imaging trials.

- NCI’s DCP grant provides funding for quality of life endpoints, cancer control and cancer prevention studies.

- Funding for trial activities 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 (NCI DCP’s grant covers this funding)
  - Non-NCI/DCTD Funding (e.g., Industry)
How Sites Receive Funding

• NCI Funds
  − NCI per case management funds are provided to all NCTN sites enrolling patients onto NCTN trials via one of 3 NCI funding mechanisms:
    1. NCTN Group rostered sites including the Non aligned affiliates
    2. NCTN LAPS (Lead Academic Participating Sites)
    3. CCOPs/MB-CCOPs (future NCORPs)

• Non NCI Funds
  − Non-NCI funding obtained by the Network Groups to supplement trial support is dispersed to all of the 3 categories of sites by the Lead Group.

  − All non-NCI funding is available to any site that meets the specific requirement for the study and is tracked by the Lead Group; therefore, no OPEN steps are needed to trigger these funds.
How Sites Receive Funding (2)

• NCI per case management funding will be made by the Network Group credited with the accrual or the equivalent will be provided via NCTN LAPS grant or CCOP grant directly.

• To receive per case funding for specific tests and/or biospecimen submissions, completion dates must be entered in the OPEN ‘funding module’ post enrollment.

• Completion dates for biospecimens should be the date the specimen was sent out. Entry of the completion date for QOLs is only required one time.

• DCP’s CCOP/NCORP funding is provided by credits and is inclusive of all trials components, unless otherwise noted.
  - More details are available at the protocol funding tab on the CTSU website for study specific information.
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.
OPEN Funding Screen (2)

- Click on the Funding sub tab at the top of the screen.
OPEN Funding Screen (3)

- The enrollment data will be displayed at the top and a funding table will be populated with each of the funding types available.

**Protocol Funding:**
- Enter the completion date for each funding type once completed.
- Completion dates cannot be prior to the enrollment date. If funding type was completed prior to enrollment date, please enter enrollment date.
- Completion dates cannot be changed after 7 calendar days of initial entry.
OPEN Funding Screen Confirmation

- Multiple dates may be entered at one time or users may return to the funding screen later to enter additional dates.
- A confirmation screen will be displayed. Completion dates cannot be changed after 7 days of initial entry.

![Funding Screen Screenshot]

- Protocol Funding:
  - Enter the completion date for each funding type if completed
  - Completion dates cannot be changed after 7 calendar days of initial entry

![Funding Table Screenshot]
Where to Find NCTN Trial Funding Information

Funding Subfolder – CTSU Website

• All NCTN protocols will have a funding subfolder on the CTSU website with a funding table and link to a funding sheet.

• Timely entry of dates in OPEN is recommended as this will record completion for per case funding.

• Funding sheets will contain additional information about non NCI funding sources if available.
### Funding Information

**A Phase III Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less.**

NCI Funding Information (other sources of funding may be available, please review the Funding Documents)

<table>
<thead>
<tr>
<th>#</th>
<th>Funding Source</th>
<th>Funding Type</th>
<th>Funding Type #</th>
<th>Specify</th>
<th>Collect Type</th>
<th>$ Value</th>
<th>CCOP Credit</th>
<th>Funding Status</th>
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<tbody>
<tr>
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<td>Bio-specimen – Tumor (Block)</td>
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<td>$150.00</td>
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<tr>
<td>4</td>
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<td>Biospecimen</td>
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<td>Bio-specimen – Whole Blood</td>
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<td>$100.00</td>
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#### Funding Documents

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<td>S1007 Funding Sheet</td>
<td>03/13/14</td>
<td>PDF</td>
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Site Resources

• The CTSU Bi-Monthly Broadcast, distributed on the 8th and 22nd of each month, will continue to be the main vehicle of communication.
  
  − Broadcasts are delivered directly via email and posted to the CTSU website.

• The CTSU Newsletter is distributed 3-4 times a year and contains detailed updates and news on CTSU initiatives.

• Link to NCTN informational documents under the Education and Resources Tab on the CTSU Members’ website.

• CTSU Help Desk - ctsucontact@westat.com
• NRG Membership - membership@nrgoncology.org
• NRG Oncology Support email - support@nrgoncology.org
Questions?
Legacy Studies

- Trials approved to transition to the NCTN have been updated with the new lead Network Group.
  - Protocol names and numbers did not change.

- The cover page for all legacy trials have been updated to include all of the participants approved to enroll to the trial.

- The navigation tree on the Protocols Tab of the CTSU website has been updated to include nodes for the NCTN and folders for the new Network Groups. Legacy trials (status=Not Complete) will be located under the new Network Group folder.

- All studies now have an updated financial page with information on per case reimbursement. Additional data may be collected in OPEN where required.
Tips for Sites Entering Funding Data

• To receive site per case funding for specific tests and/or biospecimen submissions, completion dates must be entered in the OPEN ‘funding screen’ on, or post, enrollment.

• Completion dates for biospecimens should be the date the specimen was sent out.

• Completion dates for QOLs or any testing that is required at multiple time points are only required to be entered one time and can be the initial completion date.

• Completion dates may be entered in the OPEN funding screen for any trial component that was completed after March 1st, regardless of when the patient was enrolled to the trial.

• The instructions are also available in the funding page of the CTSU website along with PPT file for more detailed information.