The NCI National Clinical Trials Network (NCTN)

RECENT CHANGES

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Agenda

- Overview
- Network Group Organization Structure
- Participation Categories
- Crediting Rules
- OPEN
- Rave
- Person Roles
- Legacy 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.
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.
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>
</table>
| Lead Academic Participating Sites (LAPS) | • LAPS Main Institution  
• LAPS Integral Component  
• LAPS Affiliates/Sub-Affiliates  
• LAPS Aligned Affiliates/Sub Affiliates (funded by Network Group) |
| CCOPs/MB-CCOPs                        | • CCOP Component  
• CCOP Sub-Component                                                                      |
| Adult Network Group                   | • Main Member  
• Affiliate  
• Sub-Affiliate                                                                          |
| Pediatric Network Group               | • Main Member                                                                           |

OR
**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.
All NCTN trials, including active legacy trials (defined as trials open prior to the start of the NCTN), use OPEN for enrollment. (With the exception of S0711 and S1201-step 2).

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

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.

Current Rave roles were carried over to the NCTN as long as the affiliated site retains an active Network Group affiliation.
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 Invitations

- A number of users may receive 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.
## 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</td>
</tr>
<tr>
<td>OPEN</td>
<td>Registrar</td>
</tr>
<tr>
<td>TRIAD</td>
<td>Site User</td>
</tr>
</tbody>
</table>

- Select roles can be maintained from the site roles tab for all NCTN groups.
Person Roster

**Person 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.
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 will be 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 will be located under the 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.
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

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CTSU Web Site

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.

- **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)

Protocol E3A06

Randomized Phase III Trial of Lenalidomide Vorucocobal Obervation Alone in Patients with Asymptomatic Smoldering Multiple Myeloma

Protocol Status: ACTIVE (Protocol Status Date: 03/24/2012)

Lead Organization: ECOG

Phase: III

CIRB Approved: No  
Canadian Sites: Protocol Not Available

Accrual:
- Target: 380
- Total: 65  As of: 02/11/14 Data Source: OPEN

Participation:
- Participation Information

E3A06 will be using the OPEN Registration System beginning 10/06/2010. 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.

Document Title | Document Date | Format | Post Date
--- | --- | --- | ---
Protocol Document (full text) | 12/20/13 | PDF | 12/02/13
Addendum #8 | 12/20/13 | PDF | 12/02/13
Recommendation of the ECOG Data Monitoring Committee - October 28, 2013 | 10/29/13 | PDF | 11/06/13
E3A06 ECOG-ACRIN Study Progress and Safety Report - May 2013 | 09/05/13 | PDF | 06/06/13
Addendum #7 | 07/03/13 | PDF | 06/06/13
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.
Coming Soon:
NCI CIRB Independent Model Sites

- In Spring 2014, institutions utilizing the CIRB will no longer be required to send documentation of initial, continuing and amendment reviews to the CTSU.

- The CTSU will be able to process an institution’s CIRB approvals by:
  - Verifying the institution is on the CIRB’s roster in RSS
  - Receiving a data feed containing the CIRB protocol approval and signatory site participation data
  - Creating 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)

- Be on the lookout for an announcement concerning this feature in the near future.
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 \( (NCP DCP’s grant covers this funding) \)
  - Non-NCI/DCTD Funding (e.g., Industry)
How Sites Receive Funding

- 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 site
  - 2. NCTN LAPS (Lead Academic Participating Sites)
  - 3. CCOPS/MB-CCOPS (future NCORP)

- 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 CTSU or OPEN steps are needed to trigger these funds.

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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 provide 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 funding is provided by credits and is inclusive of all trials components, unless otherwise noted; please refer to the protocol funding tab on the CTSU website for study specific information.
NCTN funding will fall into one of three collection types:

- **Mandatory Funding Types** – this funding is provided to all sites participating on a study. Patient enrollment itself serves as the trigger for this funding type. *No additional data entry in OPEN is required.*

- **Conditional Funding Types** – this funding is provided to sites once a certain condition or parameter is met (e.g., completed a mandatory biospecimen collection). *The site user is required to enter completion dates in the OPEN funding screen at the time of patient completion or the date a specimen was sent.*

- **Optional funding types** – this funding is provided if sites complete an optional component of the study. *The site user is required to enter completion dates in the OPEN funding screen at the time of patient completion or the date a biospecimen was sent.*
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 sub tab at the top of the screen.
The enrollment data will be displayed at the top and a funding table will be populated with each of the funding types available.

<table>
<thead>
<tr>
<th>Protocol</th>
<th>PID</th>
<th>Initials (LFM)</th>
<th>Step</th>
<th>Arm</th>
<th>Site</th>
<th>Investigator</th>
<th>Status</th>
<th>Status Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1208</td>
<td>12197</td>
<td>GR-</td>
<td>1</td>
<td>X</td>
<td>CA011</td>
<td>El-Khoueiry, Anthony</td>
<td>REGISTERED</td>
<td>01/30/2014</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Funding Type</th>
<th>Funding Type #</th>
<th>Specify</th>
<th>Date Completed (MM/DD/YYYY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biospecimen</td>
<td>1</td>
<td>Bio-specimen - Tumor (Block)</td>
<td></td>
</tr>
<tr>
<td>Biospecimen</td>
<td>2</td>
<td>Bio-specimen - Plasma</td>
<td></td>
</tr>
<tr>
<td>Biospecimen</td>
<td>3</td>
<td>Bio-specimen - Peripheral Blood</td>
<td></td>
</tr>
</tbody>
</table>

Funding Type, Funding Type # and Specify will be prefilled based on study requirements
Completion date is required
OPEN Funding Screen (4)

- Enter the date when the test was completed or biospecimen sent by clicking on the textbox to enter the date in MM/DD/YYYY format or click on the calendar icon to select a date. Click on ‘save’ after entering the dates.

![Funding Screen Image]

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

<table>
<thead>
<tr>
<th>Funding Type</th>
<th>Funding Type #</th>
<th>Specify</th>
<th>Date Completed (MM/DD/YYYY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening for Intervention</td>
<td>1</td>
<td></td>
<td>02/03/2014</td>
</tr>
</tbody>
</table>

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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.
Where to Find NCTN Trial Funding Information

Funding Subfolder – CTSU Website

- All NCTN protocols will have a funding subfolder on the CTSU web site 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.

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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DCTD</td>
<td>Base Intervention</td>
<td></td>
<td></td>
<td></td>
<td>$2,250.00</td>
<td></td>
<td>ACTIVE</td>
</tr>
<tr>
<td>2</td>
<td>DCTD</td>
<td>High Performance Intervention</td>
<td></td>
<td>LAPS Intervention</td>
<td>Mandatory</td>
<td>$4,000.00</td>
<td>1</td>
<td>ACTIVE</td>
</tr>
<tr>
<td>3</td>
<td>DCTD</td>
<td>Biopspecimen</td>
<td>1</td>
<td>Bio-specimen – Tumor (Block)</td>
<td>Conditional</td>
<td>$150.00</td>
<td></td>
<td>ACTIVE</td>
</tr>
<tr>
<td>4</td>
<td>DCTD</td>
<td>Biopspecimen</td>
<td>2</td>
<td>Bio-specimen – Whole Blood</td>
<td>Conditional</td>
<td>$100.00</td>
<td></td>
<td>ACTIVE</td>
</tr>
<tr>
<td>5</td>
<td>DCTD</td>
<td>Biopspecimen</td>
<td>3</td>
<td>Oncotype Dx Submission</td>
<td>Conditional</td>
<td>$250.00</td>
<td></td>
<td>ACTIVE</td>
</tr>
</tbody>
</table>

**Funding Documents**

<table>
<thead>
<tr>
<th>#</th>
<th>Document Title</th>
<th>Document Date</th>
<th>Format</th>
<th>Post Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>S1007 Funding Sheet</td>
<td>03/13/14</td>
<td>PDF</td>
<td></td>
</tr>
</tbody>
</table>
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
Questions?