

NCTN and NCORP Funding Information For Sites

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Agenda

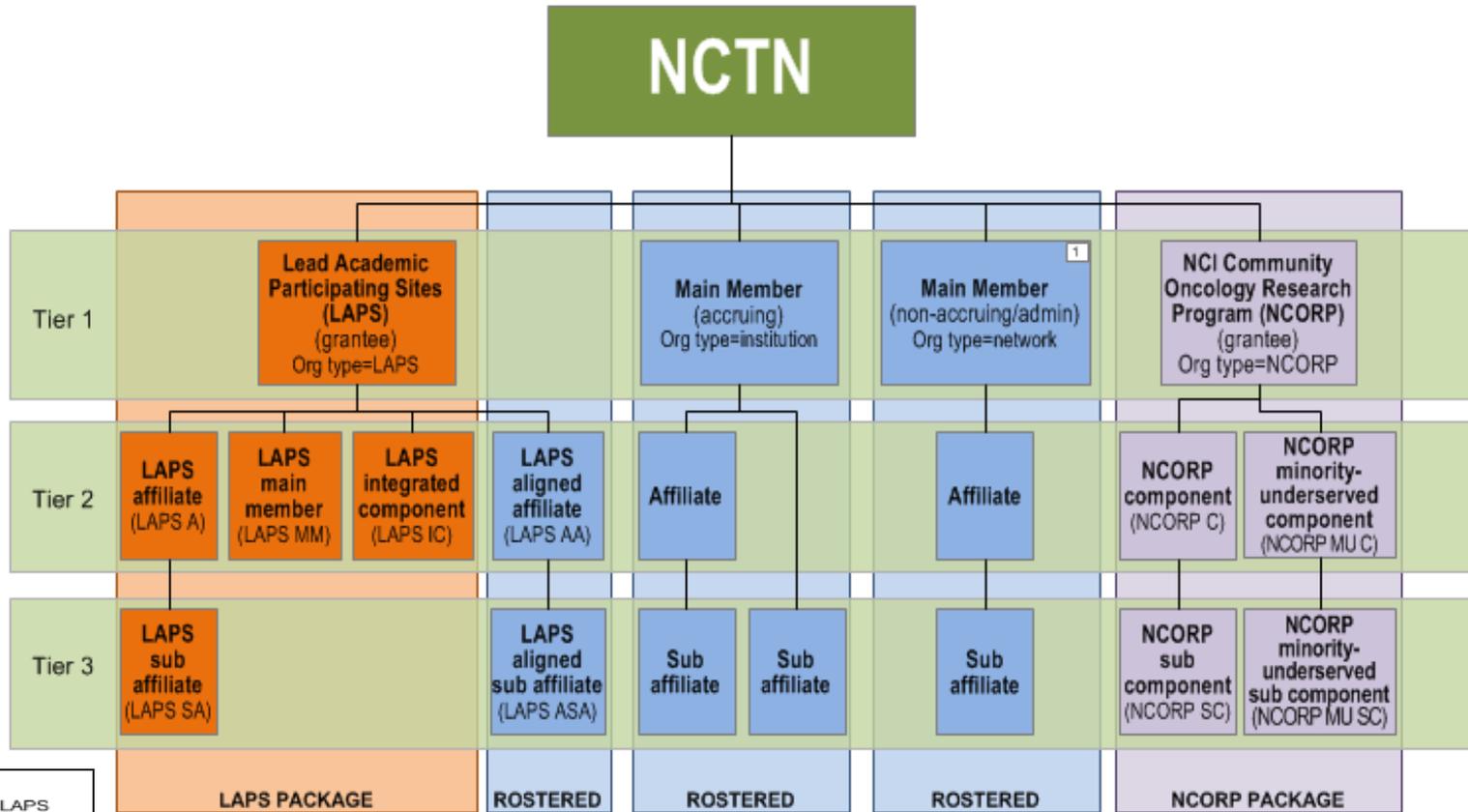
- **OVERVIEW & HOW SITES RECEIVE PER CASE FUNDING**
- **ACCESSING THE OPEN FUNDING SCREENS & WHERE TO FIND FUNDING INFORMATION**
- **NETWORK GROUPS DISTRIBUTION OF FUNDS**
- **UPDATES FROM THE CTSU TO HELP SITES WITH NCI TRIALS**

OVERVIEW

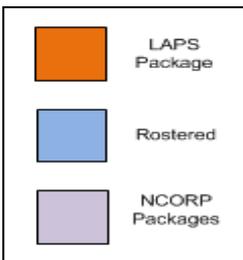
Funding in the NCTN

- NCI per case management funds are provided to all sites enrolling patients onto NCTN trials via one of 3 NCI funding mechanisms:
 1. NCTN Group Grants
 2. NCTN Lead Academic Participating Site Grant (LAPS)
 3. DCP NCORP Grant
- 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 Protocol Organization (LPO)**. All non-NCI funding is available to any site that meets the specific requirement of the study and is tracked by the Lead Group; therefore, no CTSU or OPEN steps are needed to trigger these funds (unless specified otherwise).

NCTN Organization Chart



1. Pre-approved for Main Member (non-accruing/administrative code) required from CTEP



How Sites Receive Per Case Funding

How Sites Receive Per Case Funding

- The NCTN trials will follow NCI's CTEP per case management funding principles for cancer treatment and advanced imaging trials.
- NCI's DCP NCORP Research Base grant provides funding for quality of life endpoints, cancer control and cancer prevention studies to non-NCORP sites.
- 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 (*NCI DCP's NCORP grant covers this funding*)
 - Non-NCI/DCTD Funding (e.g., Industry)

How Sites Receive Funding (con't)

- NCI per case management funding will be made by the Network Group credited with the accrual or the equivalent will be provided via the NCTN LAPS grant or NCORP Community Site grant directly.
- Non-NCI/DCTD funding will be distributed by the Lead Network Group to the Group credited with the enrollment for distribution to the sites. This funding does not require completion dates to be recorded in OPEN unless otherwise specified.

NCTN Funding Collection Types

- Mandatory Funding – 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.***
- Mandatory Request and Mandatory Event – for trials that specify that sites are required to ask a patient to participate in an optional study or trials that require a specific data or biospecimen collection at a specific event, such as recurrence, ***the Site is required to enter completion dates in the OPEN funding screen at the time of patient completion or the date a specimen was sent.***
- 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.***

Accessing the OPEN Funding Screen

Accessing the OPEN Funding Screen

- To enter data needed to trigger funding for a trial, click the history tab & search for the Patient ID (PID) associated with the enrollment. Enrollments with funding requiring completion dates in OPEN 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.

Selected Tracking # **179973** [Details](#) [Summary](#)

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
A031201	9101728	MNO	1	A	NC010	Armstrong, Andrew	REGISTERED	03/06/2015

* For registrations that have NOT been completed, please go to the [Enroll -> In Progress](#) tab.

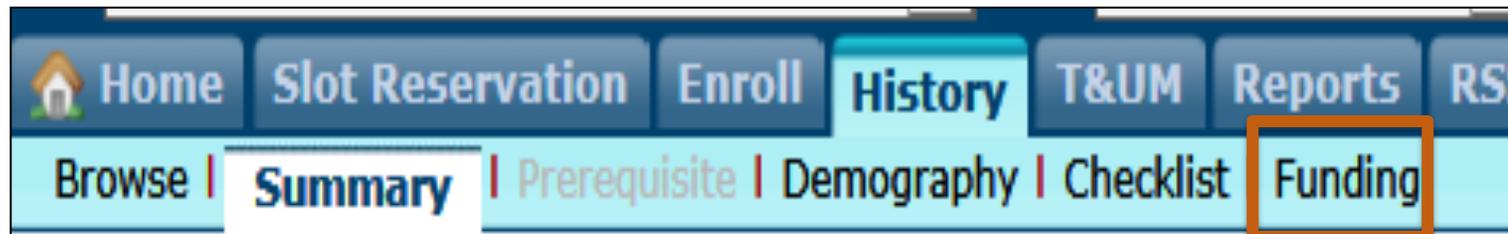
Navigation: 25 [dropdown] [icon] [Search] [Clear]

Action	V	D	Track #	Protocol	Site	Credit	Step	PID	Arm	Eligibility	Status
Selected			179973	A031201 \$	NC010	ALLIANCE	1	9101728	A	ELIGIBLE	REGISTERED

10/23/2015 11

Accessing the OPEN Funding Screen (cont.)

- Click on the Funding sub tab at the top of the screen.



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

OPEN Funding Screen

- Enter the date the test was completed or biospecimen was obtained 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 Report

Protocol Funding:

- Enter the completion date for each funding type since completion
- Completion dates cannot be prior to the enrollment date. If 2 was completed prior to enrollment date in date field.
- Completion dates cannot be changed after 7 calendar days of initial entry.

Funding Type	Funding Type #	Specify	Date Completed (MM/DD/YYYY)	Comments (300 Characters)	
Biospecimen		Biospecimen - Peripheral Blood - Whole blood (collections)	<input type="text" value=""/>	<input type="text" value=""/>	<input type="button" value="Clear"/>
Biospecimen		Biospecimen - Tumor (Block) - Metastatic tissue blocks, slides or core punches	<input type="text" value=""/>	<input type="text" value=""/>	<input type="button" value="Clear"/>
Biospecimen		Biospecimen - Tumor (Block) - Primary tissue blocks, slides or core punches	<input type="text" value=""/>	<input type="text" value=""/>	<input type="button" value="Clear"/>
Quality of Life		Quality of Life	<input type="text" value=""/>	<input type="text" value=""/>	<input type="button" value="Clear"/>

Funding Report provides funding dates entered for the patients at your site

Completion date is required

Funding Type and Specify will be prefilled based on study requirements

Comments Field allows OPEN users to enter information about funding. This information is not sent to the Groups.

OPEN Funding Confirmation

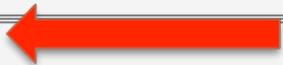
- A confirmation screen will be displayed. Completion dates cannot be changed after 7 days of initial entry.
- Timely entry of dates in OPEN is recommended as this will record completion for per case funding.

 **Information**
Funding completion date(s)/comment(s) updated. 

Funding Report

Protocol Funding:

- Enter the completion date for each funding type once completed.
- Completion dates cannot be prior to the enrollment date. If 2 was completed prior to enrollment date, please enter enrollment date in date field.
- Completion dates cannot be changed after 7 calendar days of initial entry.

Funding Type	Funding Type #	Specify	Date Completed (MM/DD/YYYY)	Comments (300 Characters)	
Biospecimen		Biospecimen - Peripheral Blood - Whole blood (3 collections)	09/17/2015 		 Clear
Biospecimen		Biospecimen - Tumor (Block) - Metastatic tissue blocks, slides or core punches	<input type="text"/> 		 Clear
Biospecimen		Biospecimen - Tumor (Block) - Primary tissue blocks, slides or core punches	<input type="text"/> 		 Clear
Quality of Life		Quality of Life	<input type="text"/> 	Patient refused. 	 Clear

[Cancel](#) [Save](#)

Tips for Entering Funding Data

- To receive per case funding for specific tests and/or biospecimen submissions, completion dates must be entered in the OPEN 'funding screen' on or post enrollment by all sites.
- Completion dates for biospecimens should be the date the specimen was obtained.
- 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.
- Some QOL funding may have an accrual cap; therefore, completion dates should be entered after the initial QOL is completed.
- Multiple dates may be entered at one time or users may return to the funding screen later to enter additional dates.

Update to the Funding Screen

A Comments column was added to the funding screen, so that notes can be added (for internal use only) regarding each per-case funding entry. Comments are not sent to the LPOs.

Home Slot Reservation Enroll **History** T&UM Reports RSS Help

Browse | Summary | Prerequisite | Demography | Checklist | **Funding**

Selected Tracking # **259874** [Details](#) [Summary](#)

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
S1207	256816	RM-	1	Blinded	IL036	Santa-Maria, Cesar	REGISTERED	08/18/2015

Funding Report

Protocol Funding:

- Enter the completion date for each funding type once completed.
- Completion dates cannot be prior to the enrollment date. If 2 was completed prior to enrollment date, please enter enrollment date in date field.
- Completion dates cannot be changed after 7 calendar days of initial entry.

Funding Type	Funding Type #	Specify	Date Completed (MM/DD/YYYY)	Comments (300 Characters)
Quality of Life		Quality of Life - Limited to NCORP sites only	<input type="text"/>	Does not apply for this patient. <input type="button" value="Clear"/>

Where to Find Funding Information

Where to Find NCTN Trial Funding Information

- NCTN and NCORP protocols listed on the CTSU website will have a funding subfolder with a funding table and link to a funding form.
- Each protocol with mandatory request, mandatory event, conditional or optional funding (*except Non-NCI/DCTD Funding – unless otherwise specified*) will use the funding screen in OPEN to collect completion dates.
- Funding forms will contain additional information about non-NCI funding sources if available.

Funding Subfolder – CTSU Website

[Home](#)

Funding Information

[LPO Documents](#)

[Drug Safety Notification](#)

[Study Agent](#)

[CIRB Documents](#)

A031201

[Add to My Protocols](#)

A Phase III Trial of Enzalutamide (NSC#766085) Versus Enzalutamide, Abiraterone and Prednisone for Castration Resistant Metastatic Prostate Cancer

Instructions

- 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 NCORP 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 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.
- See protocol funding sheet for more details and information about non-NCI funding.
- Click [NCTN Funding Instructions](#) for more information.

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

NCI Funding Sources

#	Funding Source	Funding Type	Funding Type #	Specify	Collect Type	NCTN \$ Value	NCORP \$ Value	Funding Status	Collect in OPEN
1	DCTD-DCP	Base Intervention			Mandatory	\$2,250.00	\$2,500.00	ACTIVE	No
2	DCTD-DCP	High Performance Intervention		LAPS or HP NCORP	Mandatory	\$4,000.00	\$4,000.00	ACTIVE	No
3	DCTD	Advanced Imaging		Advanced Imaging - Other - A031201-IM1	Conditional	\$250.00	\$250.00	ACTIVE	Yes
4	DCTD-DCP	Biospecimen	1	Biospecimen - Other - ST1, PP1, PP2	Optional	\$400.00	\$400.00	ACTIVE	Yes

Funding Documents

#	Document Title	Document Date	Format	Post Date
Funding				
1	A031201 Funding Sheet	01/01/15	PDF	02/18/15

NCTN & NCORP Funding Sheets

PROTOCOL XXXXXXXX

Protocol Title

Study Activation: xx/xx/xxxx

Identifies when dates need entering in OPEN to trigger funding

Funding Source and Study Component		Mandatory/ Mandatory Request or Event/ Optional	Study Specific Notes	Enter Date in OPEN?	NCTN Funding Amount per Patient (a) Standard/ LAPS	NCORP Funding Amount per Patient (b) Std/HP
Federal	Base Intervention (Standard/ High Performance (HP) LAPS & NCORP)	Mandatory		No	\$2250 / \$4000	\$2500/ \$4000
Federal						
Federal						
Total Potential Federal Funds (c)					\$ / \$	\$ / \$
Non-Federal				No		
Total Potential Non-Federal Funds (d)					\$	\$
Total Potential Funds					\$ / \$	\$ / \$

Key Points for NCORP sites

- Need to review 2 documents when assessing funding:
 - **NCI Funding Sheets** – provide all sources of applicable funding (Federal, Non-Federal and Other Federal) but no credit information
 - Study Specific Notes at bottom of document (important to review)
 - **NCORP Credit Report** - provides credit and funding information only for trial components paid for by Federal funding sources for which credits are applied
 - Review credits & funding/dollar amounts provided
- Only trial components that are funded by a Federal source are assigned credits
- Trial components funded by Non-Federal and Other Federal (e.g., BIQSFP, NCI contracts, etc.) funds will be paid directly to NCORP Site by the Lead NCTN Group or the NCTN Group credited by the enrolling site



PROTOCOL A011106

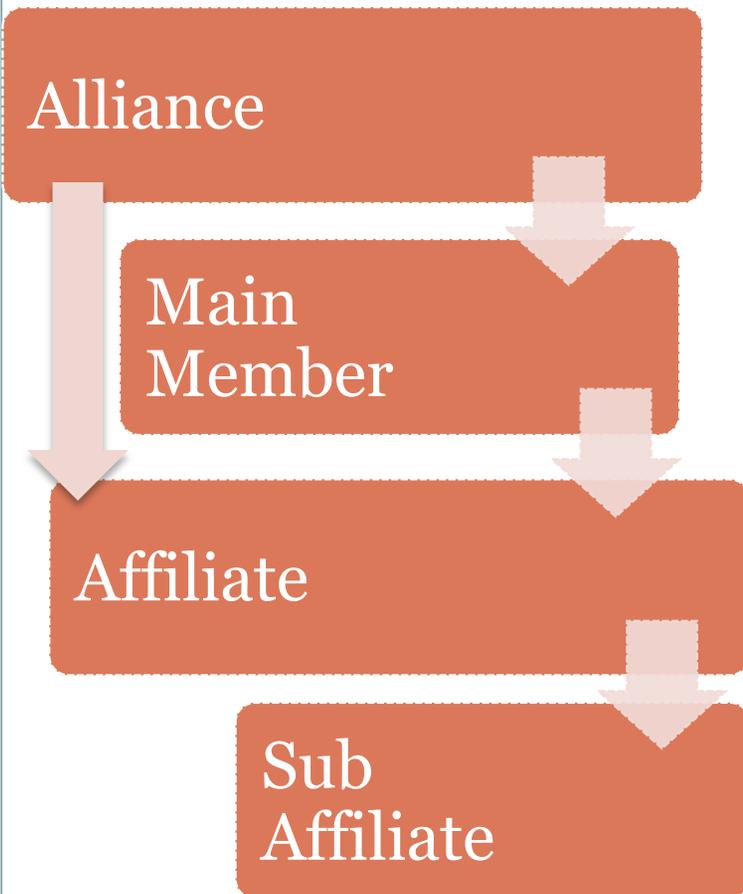
ALternate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: a phase III study

Study Activation: 12/13/2013

Funding Source and Study Component		Mandatory/ Mandatory Request or Event/ Optional	Study Specific Notes	Enter Date in OPEN?	NCTN Funding Amount per Patient (a) Standard/ LAPS	NCORP Funding Amount per Patient (b) Std/HP
Federal	Base Intervention (Standard/ High Performance (HP) LAPS & NCORP)	Mandatory		No	\$2250 / \$4000	\$2500 / \$4000
Federal	Biospecimen – Tissue – Pre-treatment core biopsy-(BIQSFP funds paid to all sites including LAPS & NCORP)	Mandatory Event	1	Yes	\$ 1,100	\$ 1,100
Federal	Biospecimen – Tissue – Week 4 core biopsy - (BIQSFP funds paid to all sites including LAPS & NCORP)	Mandatory Event	1	Yes	\$ 1,100	\$ 1,100
Federal	Biospecimen – Tissue - At time of surgery two formalin core biopsies, two frozen core biopsies, and 10 fixed tumor tissue slides	Mandatory Event	2	Yes	\$ 450	\$ 450
Federal	Biospecimen – Tissue at disease progression	Optional	3	Yes	\$ 150	\$ 150
Federal	Biospecimen – Blood - Serum, plasma and whole blood	Optional	4	Yes	\$ 150	\$ 150
Total Potential Federal Funds					\$5200/ \$6950	\$5450 / \$6950
Non-Federal	Alliance Foundation funds – Week 12 Core biopsy	Optional	5	No	\$ 557	\$ 557
Non-Federal	Alliance Foundation funds- Neoadjuvant Chemotherapy Group who receive paclitaxel- Day 2 of Cycle 1 core biopsy	Optional	5	No	\$557	\$557

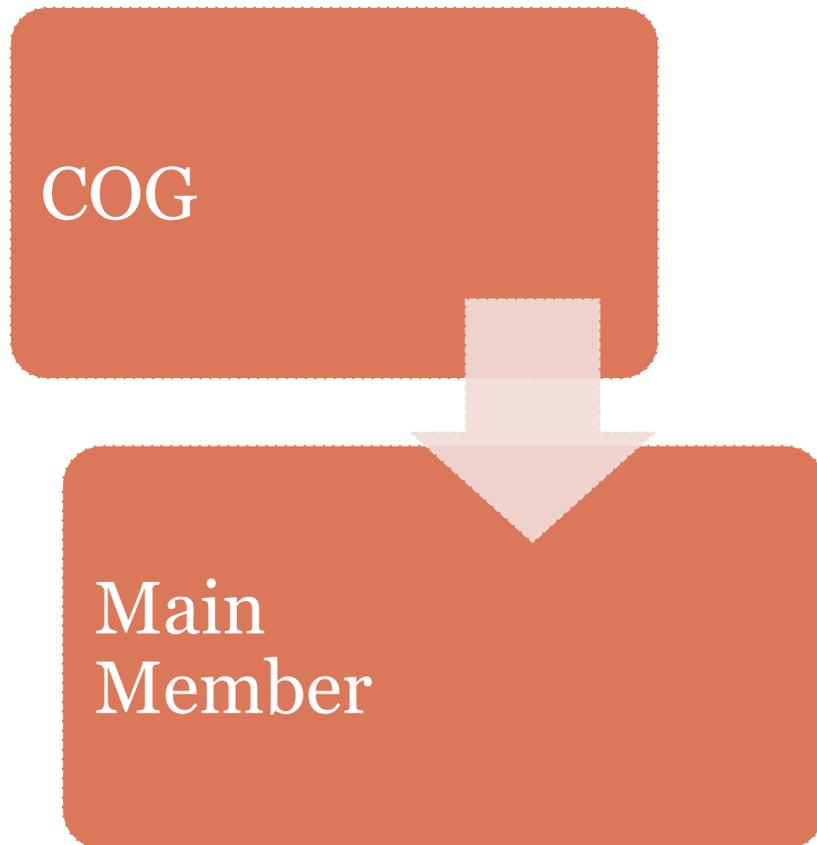
Network Groups Distribution of Funds

Alliance



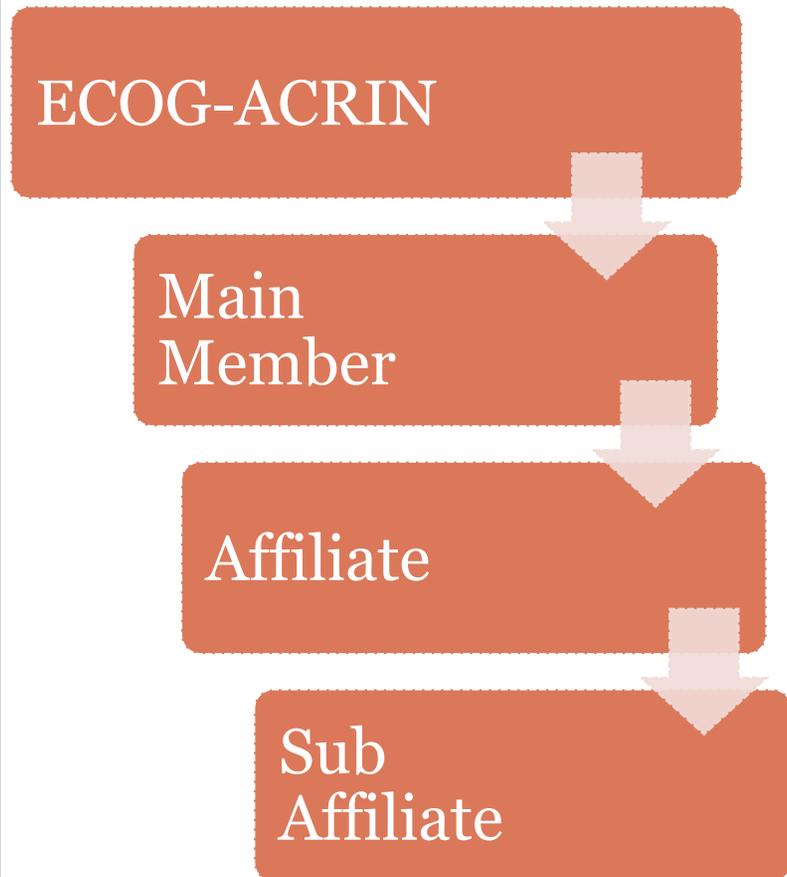
- Alliance distributes payments for accrual on a biannual basis.
 - January-June accruals paid in July.
 - July-December accruals paid in January.
- Payment is made to main members and affiliates depending on their financial relationship.
 - Main members will receive the payments for the affiliates that share a direct financial relationship.
 - Affiliates that do not have a financial relationship with its main member will receive their payments directly.
- Non-NCI funding is paid on a quarterly basis.
- Federal Payments Contact –
Amanda Welch, Financial Manager
617-525-3026
awelch6@partners.org or AlliancePayments@partners.org
- Non-Federal Payments Contact –
Sylvia Hrbek, Accounting Manager
773-702-9904 or shrbek@alliancencn.org

COG



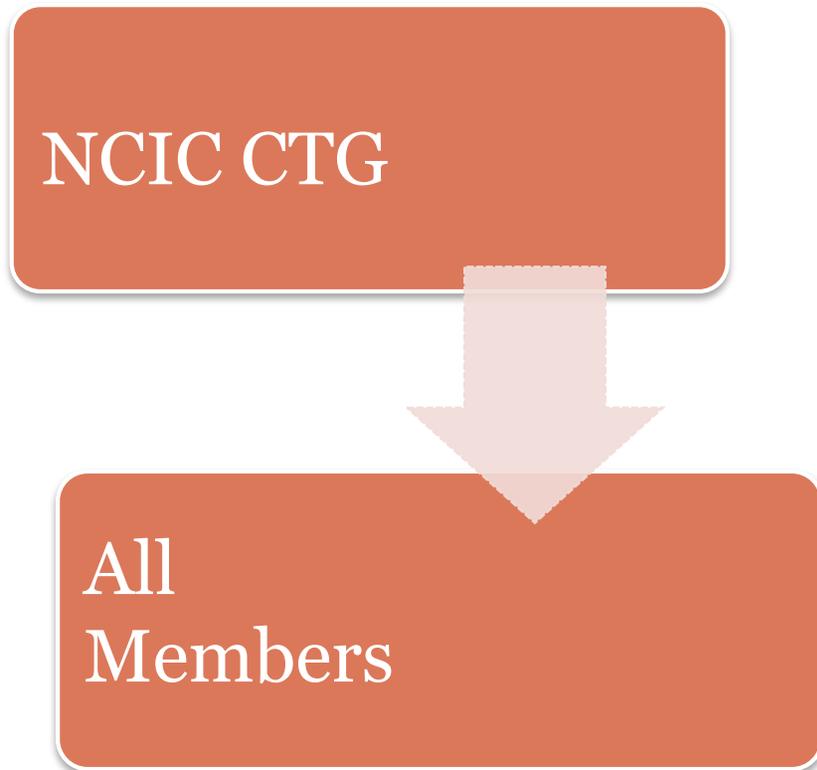
- COG distributes payments for accrual on a *quarterly basis*. Schedule for payments, is June, September, December, March. Payment is made to COG main members.
- Information on the distribution of non-NCI funding is paid on a *quarterly basis*. Schedule for payments, is February, May, August, November. Payment is made to COG main members.
- Contact Information:
 - For *Payment* questions:
 - torrensn@email.chop.edu &
 - COG_invoices@email.chop.edu
 - For *PCR detail*:
 - coylek@email.chop.edu

ECOG-ACRIN



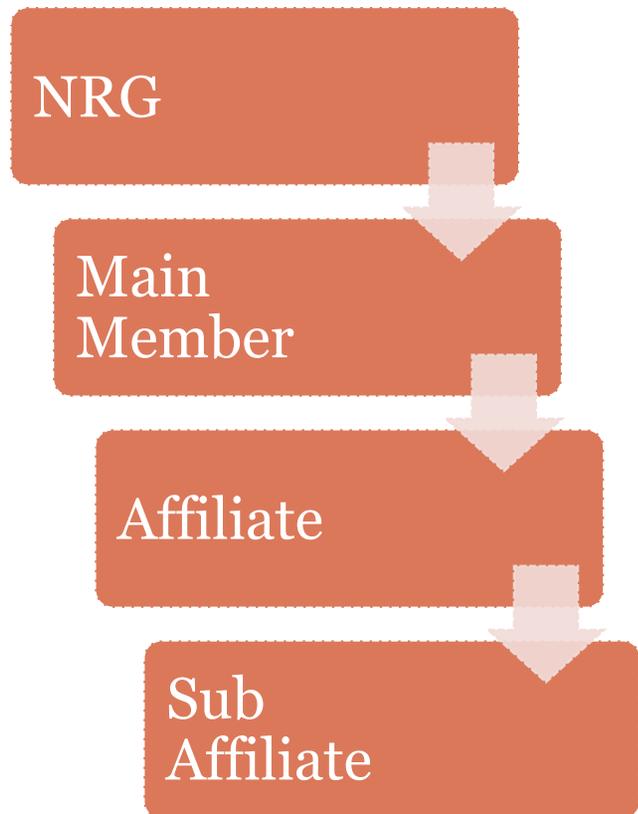
- ECOG-ACRIN's goal is to distribute payments for accrual on a *monthly basis*, commencing July 2014.
- Payment is made directly to each site, unless the site has specified an alternate payee on their Purchase Services Agreement.
- Non-NCI funding is based on milestones, with a goal of distribution monthly, commencing July 2014.
- Questions regarding the case reimbursements process can be directed to reimbursements@ecog-acrin.org

NCIC CTG



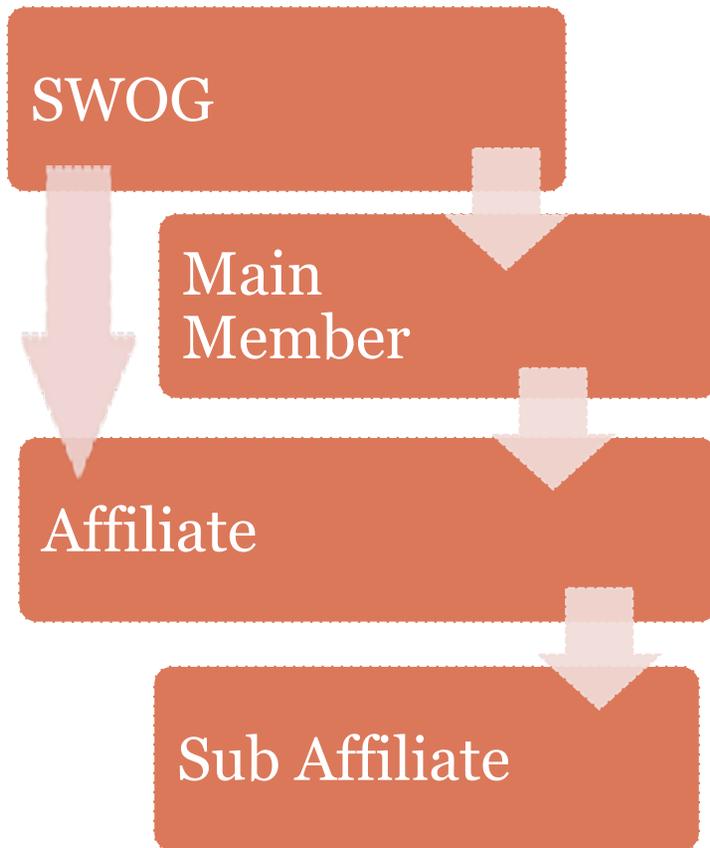
- NCIC CTG distributes payments for accrual once every 2 months. The schedule for payments are: Jan 31, Mar 31, May 31, July 31, Sept 30, Nov 30.
- Payment is made to member sites directly.
- NCIC CTG has a database application which tracks all required funding information and distributes payments.

NRG



- NCI funds for per-patient payments on studies credited to NRG Oncology are distributed on a *monthly basis*.
- Payment is made to Main Members and LAPS Aligned Affiliates based upon an active Purchased Service Agreement on file with NRG Oncology.
 - *Main Members are to make payments within their networks according to agreements with their Affiliates and Sub Affiliates.*
 - *LAPS are to make payments to their Aligned Affiliates according to their agreements.*
- Non-NCI funding to Main Members, LAPS, and NCORPs is distributed on a *monthly basis*. Specific payment information is available on the payment funding sheets located on the CTSU website.
- Information for sites can be found at Payments@nrgoncology.org

SWOG



- SWOG Group Chair's Office distributes payments for accrual to non-LAPS members & affiliates on a monthly basis.
- Payment is made to SWOG main members directly, and affiliates where appropriate, as determined by SWOG network roster.
- Contact info:
Patricia Mize, MBA
Accounting Specialist
mizep@ohsu.edu

UPCOMING FEATURES

**What New Tools Are
Being Implemented To
Help Site Efficiency?**

National Coverage Analysis

- CTSU is working with the Network Groups and Research Bases to provide National Coverage Analysis (CA) support for NCI supported trials.
- A working group is in place to:
 - Define the roles and responsibilities for developing CA documents,
 - Establish a process for creating the CA for NCTN and NCORP protocols,
 - Pilot CA documents for specified protocols on the CTSU website.
- A coverage analysis for the MATCH trial will be available on the CTSU website in November.

Webinars

- This initiative started in April 2015 with the “Access to NCTN AYA Trials” Webinar.
- Goal of the webinars is to address key concerns that affect accrual to NCI-supported trials, and raise awareness of trials among NCTN sites.
- Upcoming Webinars:
 - EAY131 MATCH webinar – Early Fall 2015
 - Lung-MAP/ALCHEMIST webinar – October 27th, 2015
 - “Sister” Breast Studies (NSABP B-51/RTOG-1304, A011202, EA1131) – December 2015

Webinars (cont.)

- Upcoming webinars will be announced via:
 - The CTSU website under the “CTSU News” Box or “Announcements” section
 - The Bi-Monthly Broadcast
 - CTSU Newsletter
- An archive of the webinars will be maintained:
 - In the E&R tab of the website under “Educational Presentations and Webinars”



Changes to the Protocol Tree

The screenshot displays a web application interface with a navigation menu at the top and a main content area. The navigation menu includes: Home, **Protocols**, Dashboard, Regulatory, OPEN, Rave, Clinical Data, Education & Resources, Collaboration, and RUMS.

The left sidebar shows a protocol tree with the following structure:

- My Protocols
 - By Site
 - By Lead Organization
 - By Cancer Type
 - By Study Type
 - By Phase
 - AYA Studies** (highlighted with a red rounded rectangle)
 - ALLIANCE
 - A031102
 - COG
 - AEWS1031
 - AEWS1221
 - AOST1322
 - ARST1321
 - ECOG-ACRIN
 - E1609
 - EAY131
 - NCTN
 - ETCTN
 - NCORP
 - CITN
 - Reports
 - Accrual Reports (highlighted with a red dashed rounded rectangle)
 - NCTN
 - ETCTN
 - NCORP
 - AYA Studies
 - Study Agent

All

AYA Accrual Report

The Adolescent and Young Adult (AYA) Accrual Report provides target and current for AYA protocols supported by the CTSU in which all protocol documentation is available on this website (protocols will display a LPO Documents folder/tab). Protocols for which CTSU funding information or CIRB documents will not be listed in this report.

Protocol Status: Phase:

Keywords (optional): Group by:

[AYA Accrual Report](#)

#	Protocol Number	Lead Group	Protocol Status	Protocol Title	Phase	Activation Date	Title
1	AEWS1031	COG	Active	A Phase III Randomized Trial of Adding Vincristine-Topotecan-Cyclophosphamide to Standard Chemotherapy in Initial Treatment of Non-Metastatic Ewing Sarcoma	III	11/22/2010	E16

CTSU Help Desk

1-888- 823- 5923

CTSUCONTACT@WESTAT.COM