

ALLIANCE CLINICAL RESEARCH PROFESSIONAL INFORMATION SESSION – CTSUS WEBSITE AND OPEN UPDATES

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Agenda

I. CTSU Website Updates

1. Protocol Tab

- New Look
- Funding Information
- CIRB Documents

2. Dashboard

3. Regulatory Tab

- Site Roles
- CIRB Preferences



2. OPEN Updates

1. Entering Funding Information

2. Transfer and Update Module (T&UM)



IMPORTANT NOTICE

Thursday October 16, 2014 - CTSU Monthly Maintenance:

CTSU Systems staff will be performing scheduled monthly maintenance on its servers this Saturday, October 18th, between 8:00 and 11:00 AM. This Website will be unavailable intermittently during the maintenance. We apologize for any inconvenience this may cause you.

CTSU Members

[Log In](#)

[Need help?](#)

Go to the [login page](#).

CTSU Registration Procedures

The [CTSU Registration Page](#) contains detailed information and links for Investigators and Associates to obtain access to the CTSU Members' website.



WE HAVE A NEW LOOK

The [Protocol List](#) contains active NCI Clinical Trials, displays detailed information, and provides links to study abstracts and clinical sites that have the trial open.

The Cancer Trials Support Unit (CTSU) is a service of the National Cancer Institute (NCI) designed to facilitate access to NCI-funded clinical trials for qualified clinical sites and to support the management and conduct of those clinical trials. CTSU Membership provides access to a wide range of information and support services for qualified investigators and research staff. The [CTSU Registration Page](#) provides additional details regarding member access. For those who are not CTSU Members this website provides a listing of active protocols that the CTSU supports along with links to resources for additional information on NCI-funded clinical trials.

Exceptional Responders Study

Now Active: [The Exceptional Responders Study](#) is a new initiative which studies the molecular characteristics of tumors of patients who had an exceptional response to a systemic cancer therapy. For more information click [here](#).

More about the Cancer Trials Support Unit

The NCI launched the CTSU in 1999 to streamline and harmonize support services for phase three Cooperative Group cancer clinical trials funded by the NCI. Since that time the scope of the CTSU has expanded to include support of multiple NCI-funded networks and clinical trials of all phases and types including cancer treatment, prevention and control, advanced imaging and correlative science studies. The CTSU collaborates with the NCI and its funded organizations to develop and support operational processes and informatics solutions leading to cost-effective solutions that reduce administrative burden on the clinical sites.

Under guidance of the NCI, the CTSU provides centralized services to support the following goals and objectives:

- Facilitate investigator and research staff participation in selected NCI multi-center programs and their clinical trials.
- Increase investigator and patient awareness and enrollment to cancer clinical trials.
- Provide standardized, integrated, and comprehensive support services to selected NCI multi-center programs.
- Identify best practices and streamline or eliminate redundant processes and procedures.
- Improve operational efficiency, enhance productivity and deliver products offering measurable business value to selected NCI multi-center programs.

NCI cancer research networks supported by the CTSU include:

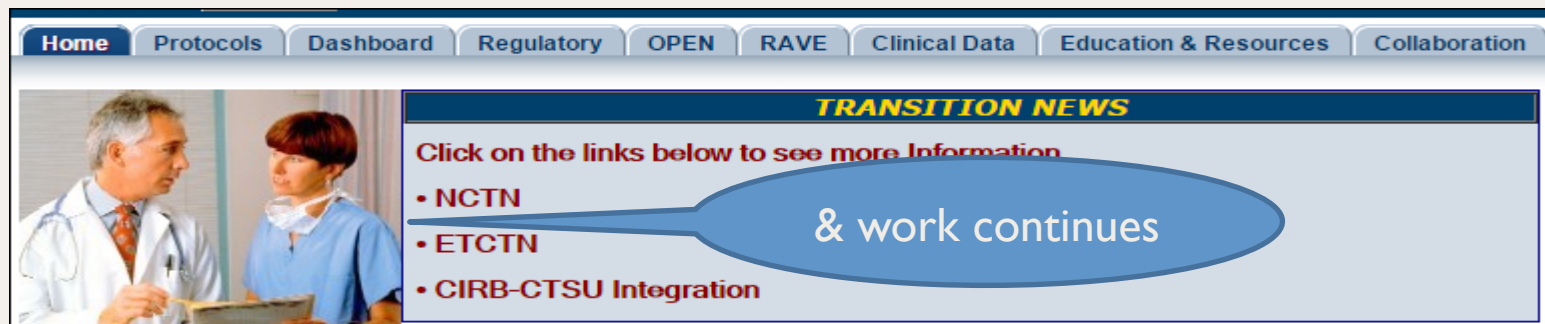
- [NCI National Clinical Trials Network \(NCTN\)](#) - is a new clinical trials research network that provides an infrastructure for NCI

ALCHEMIST

[Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials](#), a set of 3 integrated, precision medicine trials testing targeted therapy in early stage lung cancer are now active. Please refer to the [NCI ALCHEMIST Press Release](#), the [NCI ALCHEMIST Question and](#)

General Website Updates

- Revised public page
- Updates to page layout and graphics (style and color) to improve visual continuity
- Updates to web page and report formats
- Updates to the underlying database structure to improve functionality





CTSU PROTOCOL SCREENS



New Protocol Screens

Home Protocols Dashboard Regulatory OPEN RAVE Clinical Data Education & Resources Collaboration

Home Funding Information LPO Documents Drug Safety Notification Study Agent CIRB Documents [Add to My Protocols](#)

Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer

Protocol Status: ACTIVE (Protocol Status Date: 06/16/2014)

Activation Date: 06/16/2014

Lead Organization: SWOG

Phase: II/III

CIRB Approved: Yes **Canadian Sites:** Protocol Not Available

Accrual: Target: 10000
Total: 43 (In OPEN: 43)
As of: 10/08/14

Participation: [Participation Information](#)

Participation Group					
#	Org Type	Participant	Role Type	Participation Type	Start Date
1	NCTN	NRG	ALL	CROSS-NETWORK	05/28/2014
2	NCTN	ECOG-ACRIN	ALL	CROSS-NETWORK	05/28/2014
3	NCTN	ALLIANCE	ALL	CROSS-NETWORK	05/28/2014
4	NCTN	SWOG	ALL	LEAD	02/05/2014

OPEN S1400 will be using the OPEN Registration System beginning 06/16/2014. 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 S1400 utilizes Medidata Rave for data collection and submission. Authorized users can use the [RAVE](#) application to enter the clinical data for this protocol.

PROTOCOL SPECIFIC NOTES

There are no Protocol Specific Notes for protocol S1400.

Funding Subfolder

- ⊕ S1202
- ⊕ S1203
- ⊕ S1207
- ⊕ S1211
- ⊕ S1216
- ⊕ S1221
- ⊕ S1300
- ⊕ S1304
- ⊕ S1310
 - 📄 Detail, Accrual and Specific Notes
 - 📁 Funding Information
- ⊕ S1313
- ⊕ S1314
- ⊕ S1320
- ⊕ S1400
- ⊕ S1400A
- ⊕ S1400B
- ⊕ S1400C
- ⊕ S1400D
- ⊕ S1400E
- ⊕ S1406
- ⊕ S9910
- ⊕ S9921
- ⊕ S9925
- 📁 SWOG-9007
- ⊕ SWOG-L
- ⊕ TX035
- ⊕ UCC
- ⊕ USMCI
- ⊕ WAKE
- ⊕ WFUCCOP
- 📁 By Cancer Type
- 📁 By Study Type
- 📁 By Phase

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

Display inactive funding also

NCTN Funding Sources									
#	Funding Source	Funding Type	Funding Type #	Specify	Collect Type	\$ Value	NCORP Credit	Funding Status	Collect in OPEN
1	DCTD-DCP	Base Intervention			Mandatory	\$2,250.00	1	ACTIVE	No
2	DCTD-DCP	High Performance Intervention		LAPS or HP NCORP	Mandatory	\$4,000.00	1.6	ACTIVE	No
3	Industry	Non-NCI/DCTD Funding	3	Other - Baseline ophthalmic exam	Mandatory Event	\$250.00		ACTIVE	No
4	Industry	Non-NCI/DCTD Funding	4	Other - Baseline ECHO exam	Mandatory Event	\$750.00		ACTIVE	No
5	Industry	Non-NCI/DCTD Funding	5	Other - Baseline ECG	Mandatory Event	\$40.00		ACTIVE	No
6	DCTD-DCP	Biospecimen	1	Biospecimen - Tumor (Block)	Mandatory Request	\$150.00	0.06	ACTIVE	Yes
7	DCTD-DCP	Biospecimen	2	Biospecimen - Tumor (Slides)	Mandatory Request	\$50.00	0.02	ACTIVE	Yes
8	DCTD-DCP	Biospecimen	3	Biospecimen - Whole Blood	Mandatory Request	\$50.00	0.02	ACTIVE	Yes
9	Industry	Non-NCI/DCTD Funding	1	Other - Specimen submission	Mandatory Request	\$250.00		ACTIVE	No
10	Industry	Non-NCI/DCTD Funding	2	Other - Imaging submission	Mandatory Request	\$250.00		ACTIVE	No

Funding Documents				
#	Document Title	Document Date	Format	Post Date
Funding				
1	S1310 Funding Sheet	08/01/2014	PDF	07/31/2014



CIRB Documents Tab

- Home
- Funding Information
- LPO Documents
- Drug Safety Notification
- Study Agent
- CIRB Documents**

S1400

[Add to My Protocols](#)

Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer

CIRB Details

#	Documents used for CIRB approval
1	CIRB's Consent Form for Protocol Version Date 05/20/14: Screening
2	Protocol Version Date 05/20/14
3	CIRB's Consent Form for Protocol Version Date 05/20/14: Sub-Study A
4	CIRB's Consent Form for Protocol Version Date 05/20/14: Sub-Study B
5	CIRB's Consent Form for Protocol Version Date 05/20/14: Sub-Study C
6	CIRB's Consent Form for Protocol Version Date 05/20/14: Sub-Study D
7	CIRB's Consent Form for Protocol Version Date 05/20/14: Sub-Study E

- Initial Reviews
- Amendment Reviews**
- Continuing Reviews

Amendment Review Documents

CIRB Approval- Recruitment/Patient Education Materials- Lung-MAP Website

CIRB Applications

- 1 [CIRB Amendment Application \(Protocol Version Date 05/20/14\)](#)

Correspondence

- 1 [07/25/14: CIRB Approval Letter for Recruitment/Patient Education Materials: Lung-MAP Website](#)
- 2 [07/23/14: Study Chair Response Memo: Lung-MAP Website](#)
- 3 [07/18/14: CIRB Approval Pending Modification for Recruitment/Patient Education Materials: Lung-MAP Website](#)

Minutes

- 1 [Minutes - Recruitment Material Review: Lung-MAP Website \(Protocol Version Date 05/20/14\)](#)



DASHBOARD

CTSU Website Dashboard

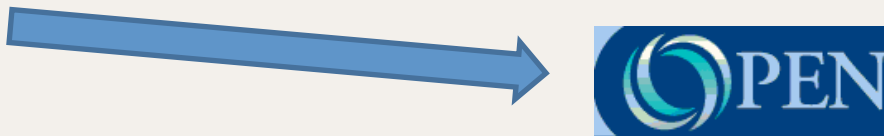
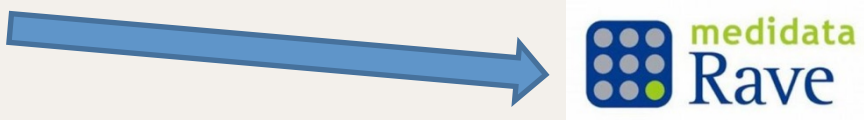
- The CTSU website is growing larger day by day due to:
 - Increasing number of protocols
 - New integrations such as the CIRB Integration
 - New funding folders for all protocols
- There was a need for site users to have a single place to view user-centric data & access systems under the CTEP Federation (applications using single sign-on)



Paradigm Shift From



- Protocols tab
- Regulatory tab
- Clinical Data tab
- OPEN tab
- RAVE tab



Paradigm Shift To

With
CTSU
Dashboard



User-centric

The screenshot displays the CTSU Dashboard interface with several data tables:

- Protocol Updates:** A table with columns: #, Protocol, Update, Post Date. It lists 10 records of protocol updates, including revisions and memorandums.
- CTEP Status Notifications:** A table with columns: #, Name, CTEP ID, Person Type, Status, Days to Suspension, CTEP Reg Exp Date, Site(s). It lists 6 individuals with their respective CTEP IDs and statuses.
- Unviewed DSNs for Studies at CTSU:** A section with a sub-table for Unviewed DSNs with columns: #, Protocol Number, Drug, Post Date, SAE Number, Adverse Events, Action. It notes that no records were found.
- Newly Posted Protocols:** A table with columns: CTSU Activation Date, Protocol Number, LPO, Title, Disease, Target Accrual. It shows one protocol for Lung Cancer.
- Site Registration at all sites:** A table with columns: #, Site, Protocol, Site Name, Comments, Missing Requirement (if applicable), Registration Status. It shows two protocols at NCI Central Institutional Review Board sites.

Protocols tab



Regulatory tab



Clinical Data
tab



OPEN tab



RAVE tab



How do I set up my Dashboard?

- Video Tutorial is available on the website



Click to open CTSU website tutorial in a separate window

The screenshot shows the CTSU Dashboard interface. On the left is a 'Navigation Menu' with links: 'Introduction to the Dashboard', 'Creating a Custom Profile', 'Portlet Level Standard Features', and 'List of Individual Portlets'. The main content area is titled 'Introduction to the CTSU Dashboard' and features a 'Featured Protocol' for N1048 (Gastrointestinal Cancer) and a 'Protocol Updates' table.

Date	Protocol	Update
11/07/13	A021101	Update #9
11/07/13	A071101	Memorandum: Site Qualification Requirement Update #9
11/07/13	PAOCT-1	Update #9
11/07/13	E5908	Memorandum: Revised Case Report Forms
11/06/13	R233	Addendum #12
11/06/13	R233	NDI Approval Letter of Addendum #12



REGULATORY TAB – SITE ROLES AND CIRB INTEGRATION

CIRB Integration

- Sites will be required to use CIRB unless a waiver is granted; information on use of the CIRB and the waiver process will be released at a later date
- Sites currently participating with the CIRB and accepting CIRB oversight for protocols no longer need to send acknowledgement of CIRB approval to the CTSU Regulatory Office
- Sites should contact the CTSU Regulatory Office at CTSURegPref@ctsu.coccg.org to set Site Preferences
- Site Preferences can be set at the network level (adult/ pediatric) and by CIRB site type (all, Signatory, per site, or per protocol)

CIRB Site Preference Screen

- RSS Browser
- Site Roles
- Site Registration
- Notification
- Protocol Requirements
- CTEP ID Search
- CIRB Site Preferences**

Instructions

The CTSU loads and maintains site preference settings for CIRB Signatory Institutions. You are viewing the site preference settings provided by your Signatory Institution to the CTSU.

If you are aligned to more than one Signatory Institution, use the drop-down to select a Signatory Institution. To view the specifics loaded for a particular site preference setting, click the setting name.

If you wish to change any of these settings, call or email the CTSU Regulatory Office at 1-866-651-CTSUS (2878) or CTSUSRegPref@ctsu.coccg.org

See Help for additional information on the Site Preference application.

To view the CIRB Affiliate and Component Institutions on the CIRB roster in RSS that are affiliated with your Signatory Institution click the "i" button.

Signatory Institution:   Help 

Fred Hutchinson Cancer Research Center

#	Network Level	Preference Settings				
1	ETCTN LAO	<input type="radio"/> ALL	<input type="radio"/> SIGNATORY ONLY	<input type="radio"/> SITE SPECIFIC	<input type="radio"/> PROTOCOL	<input checked="" type="radio"/> NONE
2	ETCTN P2C	<input type="radio"/> ALL	<input type="radio"/> SIGNATORY ONLY	<input type="radio"/> SITE SPECIFIC	<input type="radio"/> PROTOCOL	<input checked="" type="radio"/> NONE
3	NCTN Adult	<input type="radio"/> ALL	<input type="radio"/> SIGNATORY ONLY	<input type="radio"/> SITE SPECIFIC	<input type="radio"/> PROTOCOL	<input checked="" type="radio"/> NONE
4	NCTN Pediatric	<input type="radio"/> ALL	<input type="radio"/> SIGNATORY ONLY	<input type="radio"/> SITE SPECIFIC	<input type="radio"/> PROTOCOL	<input checked="" type="radio"/> NONE

NCI CIRB Educational Material

Home Protocols Dashboard Regulatory OPEN RAVE Clinical Data **Education & Resources** Collaboration

Search:

- + My Protocols
- + My Favorites [0 docs]
- + National Clinical Trials Network (NCTN) Program
- + Experimental Therapeutics Clinical Trials Network (ETCTN) Program
- + **CIRB-CTSU Integration**
- + CTSU Operations Information
- + Protocol Specific Materials
- + Audit Resources
- + Researcher Resources
- + Educational Presentations and Webcasts
- + Site Advisory Panel
- + Frequently Asked Questions (FAQs)
- + Glossary and Acronyms

CIRB-CTSU Integration

This page contains information regarding the CIRB-CTSU Integration, which went into effect on June 16, 2014 and applies to sites utilizing the NCI CIRB.

Use the [feedback button](#) to submit any questions you may have regarding the CIRB-CTSU Integration.

CIRB-Integration Documents

#	Document Title	Size	Document Date	Post Date
1	CIRB IT Integration Questions and Answers		09/05/2014	09/08/2014
2	Frequently Asked Questions (FAQs) for CIRB Institutions			07/01/2014
3	Overview of the New CTSU Regulatory Process for Institutions Enrolled in the NCI CIRB		06/25/2014	06/26/2014
4	Quick Fact Sheet: New Regulatory Process for NCI CIRB Institutions		06/13/2014	06/13/2014
5	Memorandum: CTSU Site Preference Feature		06/13/2014	06/13/2014



OPEN – PER CASE MANAGEMENT

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 Funding (e.g., Industry)



How Sites Receive Funding



- 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 or NCORP grants
- DCP's NCORP 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
- OPEN is being used to capture the funding triggers for the Adult NCTN Trials

How Sites Receive Funding



Non-NCI Funds

- Non-NCI funding obtained by the Network Groups to supplement trial support is dispersed to sites by the Lead Group (*directly or through credited 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

OPEN Funding Screen

To enter funding data, 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.

Home Slot Reservation Enroll **History** Reports RSS Form Setup Admin Help heringm@ctsuu

Browse | Summary | Prerequisite | Demography | Checklist | Funding

Selected Tracking # **177123** Details Summary

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
E1910	19082	GB-	1	A	MN008	Amatruda, Thomas	REGISTERED	10/10/2014


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

25 Search Clear


V	D	Track #	Protocol	Site	Credit	Step	PID	Arm	Eligibility	Status	Randomized Date	Registrar
Select		177098	A041202	NC010	ALLIANCE	1	9100972	3	ELIGIBLE	REGISTERED	10/09/2014 04:54 PM	ESSERL
Select		177095	A041202	NC010	ALLIANCE	0	9100972	N/A	ELIGIBLE	REGISTERED	10/09/2014 04:47 PM	ESSERL
Select		176443	A041202	NC010	ALLIANCE	0	9100263	N/A	ELIGIBLE	REGISTERED	09/03/2014 11:10 AM	HEALANDT

OPEN Funding Screen




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

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

Step 1 Registration Information: [Tracking # 177098] [Create Step 2](#) [Go to Previous Step](#) [Cancel Enrollment](#)

Protocol Number: A041202 **Protocol Title**
Patient ID: 9100972 *A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib in Patients (>/= 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL)*
Initials (LFM): OBJ
Treatment Arm: 3
Treatment Assignment Code:
Treatment Assignment Description:
Subgroup Code:
Registration Step: 1 (Randomization)
Institution: Duke University Medical Center [NC010] 
Registration Status: REGISTERED on 10/09/2014 04:54 PM EDT

Associated Persons:

Person Type	Person Name	Status
Treating Investigator	 Routh, Jonathan (48666)	ACTIVE
Drug Shipment Investigator	 Ahmed, Maleka (24344)	ACTIVE
Site Registrar	 Dillard, Erin (539779)	ACTIVE

OPEN Funding Screen

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

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

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

Selected Tracking # **177095** [Details](#) [Summary](#)

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
A041202	9100972	OBJ	0	N/A	NC010	Ahmed, Maleka	REGISTERED	10/09/2014

Funding Report

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 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)
Biospecimen	1	Biospecimen - Other - A041202-LC1	<input type="text"/> <input type="button" value="Clear"/>
Biospecimen	2	Biospecimen - Other - A041202-PP1	<input type="text"/> <input type="button" value="Clear"/>

Funding Type, Funding Type # and Specify will be prefilled based on study requirements

Completion date is required

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 can be changed for up to 7 days of initial entry

Selected Tracking # 177000 [Details](#) [Summary](#)

Protocol	PID	Initials (FM)	Step	Arm	Site	Investigator	Status	Status Date
A041202	9100972	OBJ	1	3	NC010	Routh, Jonathan	REGISTERED	10/09/2014

Information
Funding completion date(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 funding type 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)
Base Intervention			10/20/2014 <input type="text"/> <input type="button" value="Clear"/>
High Performance Intervention		LAPS Intervention	10/20/2014 <input type="text"/> <input type="button" value="Clear"/>
Quality of Life		Quality of Life - A041202-EL1	10/20/2014 <input type="text"/> <input type="button" value="Clear"/>

Tips for Sites Entering Funding Data



- 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
- To receive site per case funding for specific tests and specimen submissions, completion dates must be entered in the OPEN 'funding screen' on, or post enrollment

Tips (cont.)

- Completion dates for any testing required at multiple time points should be entered one time and can be the initial completion date
- NCORP sites are required to enter completion dates for any trial component completed after August 1st, regardless of when the patient was enrolled to the trial
- Timely entry of dates in OPEN is recommended as this will record completion for per case funding



OPEN
TRANSFER & UPDATE MODULE
COMING SOON!

Overview of OPEN v7.0 Release

- New NCI Reporting Requirements to collect additional data points to support SAE and other reporting
 - Treatment Assignment Code (TAC)
 - Treatment Assignment Description (TAD)
 - Disease Code and Disease Name
 - Subgroup
- Transfer & Update Module (T&UM)
 - Allows sites to update enrollment data post entry in OPEN and sends updated data to the LPO RandoNode and Rave
 - Data Updates Allowed
 - Transfer of patient from one site to another
 - Updates to credentialing data
 - Updates to demographic data

Disease Code

- Disease Codes will be collected on the Demography Screen in OPEN
- Current process for collection of disease code varies with each Lead Protocol Organization (LPO)
 - Part of the eligibility checklist
 - Added on the backend by LPO
- New Process:
 - This field will be a drop down box with the valid responses on the demography screen
 - Users will select the response from the provided values (*In some cases only one response may be available*)
 - If question is part of EC the field will be auto filled with response from demography screen

OPEN Screen Changes

- Demography Form
 - Added Disease Code

Standard_Method_of_Payment

* Method of Payment

PRIVATE INSURANCE

MEDICARE

MEDICARE AND PRIVATE INSURANCE

MEDICAID

MEDICAID AND MEDICARE

MILITARY OR VETERANS SPONSORED NOS

SELF PAY (NO INSURANCE)

NO MEANS OF PAYMENT (NO INSURANCE)

OTHER

Unknown

Standard NCI Reporting

* Disease Code [Select](#) [Clear](#)

Oncology Patient Enrollment Network [SUSHMITA - 09/25/14 10:38:07 AM EDT]

Lookup List of Values:

Select Value	Name	Description
<input type="text" value="10036910"/>	Prostate cancer, NOS	

TAC, TAD and Subgroup Code

Selected Tracking # **176979** [Details](#)

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status
S1400E	700147	III	1	1	MA125	Zimbler, Harvey	REGISTERED

Information

- Network Group response for tracking # **176979**
- This registration can now be found in the HISTORY section

Network Group Response(s)	
Eligibility:	ELIGIBLE
Ineligibility Reason:	None.
Patient ID:	700147
Treatment Arm:	1
Treatment Assignment Code:	
Treatment Assignment Description:	
Subgroup Code:	

Rave Standard Forms

- TAC and TAD will be added to the Step Information and Treatment Assignment Forms in Rave
- TAC and TAD will be prepopulated from the confirmation page in OPEN to the Treatment Assignment Form in Rave.

Subject: SD-V5-EC-0001

Page: Treatment Assignment - Enrollment Forms

#	Arm Name ?	Step No ?	Event description ?	Date of Intervention/Treatment Assignment ?	Event Time ?	Treatment Assignment Code (TAC): ?	Treatment Assignment Description (TAD): ?
1	1 ▲	1	Registration ▲	4 Sep 2014 ▲	04:15:25:PM EST	other ▲	TAD ▲
2	A	1	Randomization	11 Jul 2014	03:59:00:AM EDT	A2 LEVEL 6	

Subject: SD-V5-EC-0001

Page: Patient Information for NCI Reporting - NCI Reporting

Participant Subgroup Code?

SG1

Is the Patient currently receiving treatment on study??

... ▼

Performance Status (Zubrod)?

... ▼

Date of Last Treatment?

... ▼

Baseline Abnormalities Flag?

... ▼

Response Evaluation Status?

... ▼

Disease Code?

10053571

Disease Name?

Glioblastoma multiforme

Patient Transfers

- Patient transfers are currently handled through multiple processes:
 - Submitting a transfer request form to the CTSU
 - Entering transfers in LPO systems
 - Backend updates
- A new tab will be added to OPEN (the T&UM tab) which will provide a central location for OPEN users to request and manage these updates


Patient Transfers (cont.)


- Automate and standardize the manual process currently being used for patient transfers and data updates across all LPOs
 - Ability for sites to view the eligible investigators and credit groups during patient transfers
 - All patient transfers will be tracked centrally in OPEN
 - The audit trail (previous value, new value) of data changes and patient transfers will be available in OPEN

T&UM – Create New Screen


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

In Progress | **Create New** | History | Help Tool

 The Transfer and Update Module(T&UM) handles data update requests (involving updates to a patient's institution, credentialing data, and demographic data) for completed patient enrollments that are maintained in OPEN.



 [Click here](#) to access the tool for locating new sites for moving patients.

Select the type of T&UM request that you would like to perform:

T&UM Request Type	Description
<input checked="" type="radio"/> Site Transfer	Update the institution associated with a patient enrollment (this may involve updates to credentialing data).  For changes to a patient's institution, the transferring sites must initiate a conversation with potential receiving sites on accepting their patients, and confirm agreement prior to initiating the site transfer process in the T&UM tab of OPEN.
<input type="radio"/> Credentialing Data Update	Update credentialing data for a patient that will remain at the same institution.
<input type="radio"/> Demographic Data Update	Update demographic data for a patient.

Data for Transfer Request

Site Transfer Request

? * Receiving Institution CTEP ID:  

? Institution Name: Saint Nicholas Hospital

? Protocol Number: E2607

? Protocol Title: A Phase II Trial of Dasatinib in KIT-Positive Patients with Unresectable Locally Advanced or Stage IV Mu

? * Requested Treating Investigator: ▼

? * Receiving Institution Contact: ▼

? * Case Status: ▼

? * Transferring Site Contact Person: ▼

? Office Phone: (763) 581-2946

? Email:

? * Comments

Can select
investigator and
site contacts from
drop down

Back

Cancel

Submit

Receiving Institution Screen

[Site Transfer Request] T&M Information for Request ID: TUM-000000161 Refresh

Review Patient Information

- Network Group Patient ID: 26104
- Protocol Number: E2607
- Step: 1
- Treatment Assignment: A
- Protocol Title: A Phase II Trial of Dasatinib in KIT-Positive Patients with Unresectable Locally Advanced or Stage IV Mucosal, Acral and Vulvovaginal Melanomas

Review the Request from the Transferring Site

- Request Type: SITE_TRANSFER
- Transferring Institution CTEP ID: MN008
- Transferring Institution Name: Abbott-Northwestern Hospital
- Receiving Institution CTEP ID: WI022
- Receiving Institution Name: Saint Nicholas Hospital
- Requested Treating Investigator: Jaslowski, Anthony John (20973)
- Receiving Institution Contact: Cimino, Teresa (500564)
- Case Status: ACTIVE_TREATMENT
- Transferring Site Contact: Alexander, Nicole (526210), nicole.alexander@parknicollet.com
- Transferring Site Comments: patient transfer request

(If Accepting) Select the Persons associated with the Patient

- Only one treating investigator* and one drug shipment investigator can be associated
- Press to add a person, or press to remove
- If a shipping investigator is not selected, the shipping address will default to the treating investigator address
- Protocol specific instructions: Protocol E2607 has the following association(s):
Treating Investigator (required), Site Registrar (optional), Contact person sample submission (required). To add optional persons, please click the green plus icon.
- Click to refresh the Person Names

Action	Person Type*	
	Contact person sample submission	- select -
	Treating Investigator	Jaslowski, Anthony John [20973] [ALLIANCE, COG, CTSU, ECOG-ACRIN]
	Site Registrar	Davies, Brenda L. [509653] [ALLIANCE, COG, CTSU, ECOG-ACRIN]

(If Accepting) Select the Credited Group and Credit Investigator

- Network Group Credit: ECOG-ACRIN
- Credit Investigator: - select -

Provide the Contact Information for the Individual at the Receiving Site

- Receiving Site Contact: Cimino, Teresa [500564] [ALLIANCE, COG, CTSU, ECOG-ACRIN]
- Office Phone: (920) 884-3483
- Email: Teresa.Cimino@hshs.org

Provide Comments Regarding this Request

- Reviewer Comments:

Back Reject Request Accept Request

Message from webpage



You are about to accept responsibility for the care of the Transferring Institution's patient. Ensure that the Transferring Institution has no outstanding data delinquencies or queries for the patient.

This request will be ACCEPTED. The request will be submitted to the Lead Protocol Organization for review (if configured for LPO review).

Do you want to continue?

OK

Cancel

Transfer Accepted

Selected Tracking # **177056** [Details](#)

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
E2607	26104	WJ-	1	A	MN008	Bailey, Cheryl	REGISTERED	10/07/2014

Information
 The Site Transfer request **TUM-000000161** has been **ACCEPTED**.
 The Lead Protocol Organization has been notified that this request is pending their review.

[Site Transfer Request] Summary Information for Request ID: **TUM-000000161** [In-Progress Browser](#) [Refresh](#)

Request Type: Site Transfer Request
Request Number: TUM-000000161
Registration Tracking Number: 177056 [i](#)
Status: **ACCEPTED**
Created By: ALEXANDERN on 10/15/2014 10:33 AM EDT
Modified By: DAVIESB on 10/15/2014 02:29 PM EDT
Next Step: [The Lead Protocol Organization will review the request](#)

Request Details from the Transferring Site

Transferring Institution CTEP ID: MN008 [i](#)
Receiving Institution CTEP ID: WI022 [i](#)
Requested Treating Investigator: Jaslowski, Anthony John (20973) [i](#)
Receiving Institution Contact: Cimino, Teresa (500564) [i](#)
Case Status: ACTIVE_TREATMENT
Transferring Site Contact: Alexander, Nicole (526210), nicole.alexander@parknicollet.com [i](#)
Transferring Site Comments: patient transfer request

Response Details from the Receiving Site

	Previous Value - (MN008)	Updated Value - (WI022) NEW
Contact person sample submission	Haas, Audrey (501192)	Cheslock, Jolene A. (500331) ▲
Treating Investigator	Bailey, Cheryl L. (25566)	Jaslowski, Anthony John (20973) ▲
Site Registrar	Haas, Audrey (501192)	Davies, Brenda L. (509653) ▲
Network Group Credit	ECOG-ACRIN	ECOG-ACRIN
Credit Investigator	Bailey, Cheryl L. (25566)	Minehan, Kiernan J. (22508) ▲
Express Courier Account Name	--	--
Express Courier Account Number	--	--

Receiving Site Contact: Cimino, Teresa (500564), Teresa.Cimino@hshs.org [i](#)
Receiving Site Comments: accept
Review Decision: **ACCEPTED**

Demography Updates

- The following demography data points can be updated:
 - Patient initials
 - DOB
 - Ethnicity
 - Gender
 - County of Residence
 - Zip Code
 - Race
- Disease code cannot be updated

Approvals for Transfers

- Transfers may be configured for auto approval or LPO approval
- Auto approval – once the transfer passes all of the validation checks the transfer is complete and emails will be sent to the sites and LPO
- LPO Approval – LPO will receive notification of pending transfer requests for Group approval. Once approved, emails will be sent to the sites

Notifications

- Automated e-mail notifications:
 - Between transferring sites
 - To LPOs for transfers, person updates, and demographic updates
 - To requestor after rejection or acceptance of request for transfer or demographic update

T&UM Access

- Persons with an OPEN registrar role will have write access to T&UM module
- Audit trails will be maintained on all request and data changes



T&UM Validation Checks

- Patient Transfer Checks
 - The receiving site must be approved for the protocol the patient is enrolled on
 - For closed protocols, the receiving site must have an IRB approval on file with the CTSU Regulatory Office
 - The receiving site must be a member of the participating organization that is receiving credit
 - The receiving investigator must be on the roster at the receiving site

T&UM Validation Checks

- Credentialing Checks
 - Investigators must be active with CTEP
 - Credited investigators must be active on the roster of the credited group at the enrolling site
 - Treating and shipping investigators must be active on the site's roster participating on the protocol
 - Associates must be active and on a participating roster at the site


When Can You Start Using the T&UM?

- OPEN Release is scheduled for November 6th
- Each LPO will determine when they will begin to use the T&UM for their trials
- Each LPO will decide if LPO approval is required for patient transfers or updates
- Information will be available on the OPEN Home Page, the OPEN tab of the CTSU website, and in the Bi-Monthly Broadcast



Training



- The OPEN Site User Guide will be updated to include the T&UMs
- A quick reference guide will be available on the OPEN Home Page and the OPEN tab of the CTSU website
- A T&UM section will be added to OPEN Site Training Video 

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
- Links to NCTN informational documents under the Education and Resources Tab on the CTSU Members' website
 - *CTSU Help Desk - ctsucontact@westat.com*

Questions?

