



ALLIANCE GROUP MEETING

November 3, 2016
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Agenda

- Regulatory Submission Portal
- Initiatives
 - National Coverage Analysis
 - Site Audit Reporting
 - Ongoing Initiatives
- Public Contact Information
- Website Updates
 - CRISP
 - Online Agent Ordering
 - IROC Credentialing Form



REGULATORY SUBMISSION PORTAL

Regulatory Submission Portal

- Allows regulatory documents to be sent by:
 - Website upload, *or*
 - Fax or Email with Barcode Cover Page.
- Streamlined communication
 - Web-tracking of submissions with tracking ID numbers and codes.
 - View images of submissions and monitor progress with real-time status updates.
- Ability to submit and access records for institutions to which users are affiliated on a Network roster as well as for their parent and child sites.

Where is the Regulatory Submission Portal?

The screenshot displays the CTSU website interface. At the top, the CTSU logo is on the left, and navigation links (Home, Contact, Feedback, Public Site, Log Out) and the version number (Version: 5.4.0.0) are on the right. Below the header, a user login area shows 'Welcome Megan K. Rossmann.' and a search bar. A main navigation bar includes 'Home', 'Protocols', 'Dashboard', 'Regulatory', 'OPEN', 'Rave', 'Clinical Data', 'Education & Resources', 'Collaboration', and 'RUMS'. A dropdown menu for 'Regulatory' is open, listing 'RSS Browser', 'Site Registration', 'Notification', 'Protocol Requirements', and 'Regulatory Submission'. The 'Regulatory Submission' option in the dropdown is highlighted with a red box. In the main content area, a 'Regulatory Submission' button is also highlighted with a red box. The left sidebar contains a tree view with 'RSS Browser' selected, showing a list of items including 'Rossmann, Megan K. (50)', 'CTSU: Cancer Trials Su', 'Regulatory and Roster F', 'Resources', 'RSS Announcements', and 'Contact Information'. The main content area displays a message about automated e-mail notifications and a link to 'Navigation Instructions for the RSS Browser Tree'.

Submitting your Regulatory Submission

Regulatory Submission Portal

[Add New Submission](#) [Help](#)

Tracking Code: Packet Status: Submission Date: Site: Protocol: Submitted By:

Enter Tracking Code Open Submissions Submitted in last 3 days All Sites All Protocols My Submissions

Regulatory Submission Tracking

#	Packet ID	Packet Status	Submission Date	Site(s)	Protocol(s)	Submitted By	Actions
No records were found that matched the criteria							

[Contact Us](#) [Disclaimer](#) [Accessibility](#) [Viewing Files](#) [External Resources](#)

For complete instructions on using the Portal including a list of all “Packet Status” types, review the Regulatory Submission Portal User Guide, by clicking the Help Icon indicated above.

Select Sites and Protocols

New Regulatory Submission

STEPS

1. Select Sites and Protocols
2. Select Submission Priority
3. Select Submission Method
4. Review and Submit Packet

1. Select Sites and Protocols | 2. Select Submission Priority | 3. Select Submission Method | 4. Review and Submit Packet

Previous Next Discard

Please tell us the site(s) and protocol(s) for the regulatory documents being submitted.

Select either an individual site and protocol or groups of sites and protocols then click the Add to Cart button. Add all necessary site and protocol selections to your cart then click the Next button. When submitting institution-specific documentation, the protocol field should be left blank. When submitting person-specific documentation, both the site and protocol fields should be left blank.

Sites:
4 items checked

Protocols:
Select additional Protocol

Add To Cart Reset

#	Site	Protocols	Actions
1	Halifax Health Medical Center-Centers for Oncology (FL001)	EAY131	
2	Mayo Clinic Cancer Center LAO (LAO-MN026)	EAY131	
3	Legacy Meridian Park Hospital (OR004)	EAY131	
4	Legacy Salmon Creek Hospital (WA179)	EAY131	

Optional: Add message regarding submission

Previous Next Discard



Select Submission Method

New Regulatory Submission

STEPS

1. Select Sites and Protocols
- ✓ 2. Select Submission Priority
3. Select Submission Method
4. Review and Submit Packet

Priority: Response to CTSU:

1. Select Sites and Protocols | 2. Select Submission Priority | 3. Select Submission Method | 4. Review and Submit Packet

How would you like to send the documents?

I have the documents ready and would like to upload them now

I would like to print a cover page and fax or email in the documents

Please upload your documents.

Accepted file extensions are TXT, PDF, TIF, TIFF, DOC, DOCX, XLS, XLSX, PPT
Accepted cumulative size limit of all files 5 MB

- Drag and drop files here, or
- Use "Select" button to select files

Two Options:

1. Direct upload

-OR-

2. Fax or Email with unique cover page

Example of Email/Fax Submission Confirmation Page

New Regulatory Submission

STEPS

- ✓ 1. Select Sites and Protocols
4 sites selected
FL001 (1) LAO-MN026 (1) OR004 (1)
WA179 (1)
- ✓ 2. Select Submission Priority
Priority: **Normal** Response to CTSU: **No**
- ✓ 3. Select Submission Method
Submission Method: **Fax/Email**
- 4. Review and Submit Packet

1. Select Sites and Protocols 2. Select Submission Priority 3. Select Submission Method 4. Review and Submit Packet

Previous Next Discard

Tracking Code for the submission is **SCT-0001831893**

Submission details saved successfully. Click the "X" button on the upper right corner to close the window.

[Click here to download fax cover page](#)

Previous Next Discard

The cover page has a special barcode and must accompany your submission. The first page of the cover sheet outlines instructions for submission, including the fax number and email address to send submissions.

IMPORTANT NOTE: This fax number and email address are new and do not match the fax and email utilized for non-Portal regulatory submissions.

Regulatory Submission Portal

Helpful Tips

- **File Format:** due to technical limitations files with the following characteristics will NOT be accepted:
 - Exceeding 20MB in size;
 - PDF files containing electronic signature fields;
 - Files with more than one extension (e.g. FileName1.pdf.jpg);
 - File names containing spaces (names must be composed of alpha and numeric characters and underscores);
 - Zip files;
 - Inclusion of an e-mail imbedded with attachments;
 - File names exceeding 35 characters in total; *and*
 - File extensions that do not accurately reflect the type of file (e.g. a text file has a .pdf extension).



INITIATIVES

National Coverage Analysis (NCA) Initiative

- NCA is a review of all tests, procedures and interventions associated with a clinical trial to determine which are 'billable' to a third party
 - Provided as guidance documents to assist sites with billing compliance;
 - Developed using NCCN guidelines and Medicare coverage determinations; *and*
 - Developed in collaboration with the NCTN lead groups, NCORP research bases and billing compliance consultant.
- NCAs are developed and maintained for NCTN Phase III treatment trials, select Phase II studies and cross network NCORP cancer control and prevention trials.
- New and amended NCAs are announced in the CTSU Bi-Monthly Broadcast.
- NCAs and education materials are located under the protocol-specific funding tabs of the CTSU website.
- Sites are responsible for verification and modification of the NCA in compliance with institutional guidelines and local coverage determinations.

Where to Find NCA Information

Home **Funding Information** PO Documents Drug Safety Notification Study Agent CIRB Documents

NCI [IRBManager](#) [Add to My Protocols](#)

A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib [NSC #761968], Crizotinib [NSC #749005], Savolitinib [NSC #785348], and Sunitinib [NSC #736511]) in Metastatic Papillary Renal Carcinoma (PAPMET)

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 on the [NCTN](#) and [NCORP Funding Instructions](#) for more information.

Coverage Analysis

- National Coverage Analysis (NCA) documents will be posted to the protocol specific funding folder for new NCTN Phase III treatment trials and select Phase II studies, as well as cross network NCORP cancer control and prevention trials activated after May 1st, 2016.
- The NCA is provided as a guidance tool for sites to assist with billing compliance. Institutions that chose to utilize this tool are responsible for the verification and modification of the coverage analysis in compliance with their institutional guidelines and local coverage determinations.
- Click on the National Coverage Analysis [FAQs](#) or the [National Coverage Analysis - CTSU Initiative Slides](#) for more information.

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

Display inactive funding also

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	\$2,260.00	\$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-DCP	Biospecimen		Biospecimen - Tissue	Mandatory Request	\$100.00	\$100.00	ACTIVE	Yes
4	DCTD-DCP	Biospecimen		Biospecimen - Plasma - (4 time points)	Mandatory Request	\$100.00	\$100.00	ACTIVE	Yes
5	DCTD-DCP	Biospecimen		Biospecimen - Serum - (4 time points)	Mandatory Request	\$100.00	\$100.00	ACTIVE	Yes

Funding Documents

#	Document Title	Document Date	Format	Post Date
Funding				
1	S1500 Funding Sheet	3/16/2016	PDF	4/6/2016
2	S1500 Coverage Analysis Worksheet	4/6/2016	Excel97	4/20/2016

NCA Initiative Info

Coverage Analysis

Site Audit Reporting

- Developed with the Clinical Trials Monitoring Branch (CTMB) to provide a more uniform, streamlined approach for accessing Source Data Verification (SDV) in Medidata Rave®.
- Goals:
 - Ability to electronically capture SDV activity in Rave;
 - Support transition from a paper-based site audit process to unified electronic process, creating a pathway to risk-based monitoring/auditing; *and*
 - Develop uniform workflow for Lead Protocol Organizations (LPOs) on pre/post SDV activities (e.g., sending study invitations to monitors, managing audit close-out, and enabling cross-group auditing).
- Pilot Phase with Alliance, NRG and SWOG is wrapping up at the end of this year.

Ongoing Initiatives

- **Data Quality Portal**
 - Allows sites to view data delinquency and queries across Rave-supported trials (if Rave Calendaring is implemented);
 - Alliance has participated in the piloting activities;
 - Production roll out is planned for the end of this year, more information will be available in the bimonthly broadcast;
 - A user guide will be available for sites once the DQP is in production.
- **Serious Adverse Event (SAE) Integration**
 - Allows entry of Adverse Events (AEs) in Rave with real-time recommendation for completing an expedited report based on protocol specific rules.
 - A071102 is part of the current pilot. A second pilot will begin in the next few months. This pilot will launch the integration between Rave and CTEP-AERS



PUBLIC CONTACT INFORMATION

Public Contact Information (I)

- Public research contact information is collected on participating site/protocol Principal Investigators (PIs) for display on Cancer.gov and ClinicalTrials.gov websites, in order to support investigator and patient searches of oncology trials and provide a point of contact for additional information.
- If an investigator or site public contact is not available,
 - LPO public contact is provided if the site is a member of the LPO, *or*
 - CTSU contact is provided if the site is not a member of the LPO.
- Please note that at this time, the CTEP and CTSU databases do not have the capability of supporting protocol, investigator, or department specific public research contact information.

Public Contact Information (2)

- At the time of initial site registration **Approval** in the Regulatory Support System, participating site and public contact information is provided to the Clinical Trials Reporting Program (CTRP) by the CTSU.
- CTRP provides the participating site and public contact information as follows:
 - To Cancer.gov for all NCI-supported studies;
 - To ClinicalTrials.gov for studies under a CTEP held IND; *and*
 - To the LPO for non-CTEP held IND studies, but the LPO is responsible for updating the information on ClinicalTrials.gov

Public Contact Information (3)

- NCI created a new programming tool* which makes participating site data available to third parties, thereby expanding opportunities for patients and doctors to locate NCI trials
 - Cancer.gov now utilizes this programming tool to enhance searching capabilities
 - As a result of this improved search function, the number of Cancer.gov users is expected to increase and accurate contact information is crucial

**Sites interested in incorporating the programming tool (Application Programming Tool (API)) to enhance their local trial search application can access it at <https://clinicaltrialsapi.cancer.gov/v1/>*

Public Contact Information (4)

- Public feedback supports the use of central public contact information for participating sites to improve the ability of patients and their physicians to ask questions and receive timely responses.
- Central contact information may include:
 - Central Phone No: such as: 1-800-CTR-IALS; and/or
 - Central email address: such as:
clinicaltrials@cancercenter.edu

Public Contact Information: What can you do now?

- Check the CTSU website for your current CTEP site codes and their current public research contact information.
- Within your institution, determine the **single best** public research phone and public research email for each of your CTEP site codes.
- Remember that **institution-specific** public research contact information should apply for **all** CTEP and DCP-sponsored studies active at that CTEP site code including:
 - all NCTN adult clinical trials (e.g., ALLIANCE, ECOG-ACRIN, NRG, SWOG)
 - all NCTN pediatric clinical trials (e.g., COG)
 - all NCORP research base clinical trials (e.g., WAKE, URCC), *and*
 - all ETCTN early phase clinical trials (e.g., LAO, EDDOP).

Locating Public Contact Information

The screenshot shows the CTSU RUMS interface. At the top, the logo for the Cancer Trials Support Unit is visible, along with the text "A SERVICE OF THE NATIONAL CANCER INSTITUTE". The user is logged in as Martha Hering, and the interface shows various navigation tabs including Home, Protocols, Dashboard, Regulatory, OPEN, Rave, Clinical Data, Education & Resources, Collaboration, and RUMS (highlighted with a red box). Below the navigation, there are tabs for Person Roster Browser, Org Roster Browser, CTEP ID Search, and Tracking. The main content area displays a table of the ALLIANCE Roster. The first row is highlighted, and a red circle is drawn around the information icon in the first column. A modal window titled "Person Detailed Information" is open, showing details for Purvi Gada (CTEP ID 41767). The "CONTACT INFO" section of the modal is highlighted with a red box, showing the Public Research Email (MMCCOP@parknicollet.com) and Public Research Phone ((952) 993-1517).

ALLIANCE Roster

Person Name	Person Type	CTEP ID	CTEP Status	CTEP Status Date	Site	Roster Status	Roles
Gada, Purvi	Investigator	41767	Active	07/19/2016	METROMIN	Active	Investigator

Person Detailed Information

Gada, Purvi (41767)

Name	Gada, Purvi	CTEP ID	41767
NCI Site #	MN129	Site Name	Minnesota Oncology Hematology PA-Chaska
NCI Status	Active	Expiration Date	08/24/2017

CONTACT INFO

Public Research Email	MMCCOP@parknicollet.com
Public Research Phone	(952) 993-1517

Updating Public Contact Information

- To update CTEP site code specific public contact information, email CTEP's ECU Help Desk at ecuhelpdesk@mail.nih.gov and provide
 - CTEP site code and name
 - Public research contact phone
 - Public research contact email
- Other Issues
 - Contact the CTSU Help Desk
 - Will assist to identify source of discrepancy and forward to appropriate contact

Public Contact Information - Future Plans

- Support new Cancer.gov search application by encouraging use of central public contacts for an institution such as:
 - Central Phone - 1-800-CLT-RIAL
 - Central E-mail - clinicaltrials@cancercenter.edu
- Enhance the options for maintaining public contact information (e.g., protocol and site specific *or* investigator and site specific).
- Improve visibility of public contact information on the CTSU website.



WEBSITE UPDATES

CTSU Report and Information Subscription Portal (CRISP)



CRISP Notifications

The screenshot shows the main content area of the portal. At the top, there's a header with the CTSU logo and the title "CTSU Report and Information Subscription Portal". Below this, there are buttons for "Add New" and a link for "CRISP User Guide". A navigation bar contains three tabs: "My Subscriptions", "Inactive Subscriptions", and "View Subscribed Messages History". The "My Subscriptions" tab is active, displaying a table with subscription details.

#	Notification Subject	Frequency	Subscriptions Settings	Action
1	Accrual Updates for Selected Protocols at your Site	DAILY	Lead Org: ALLIANCE Protocol Number: A011202, A011203	[Edit] [Delete]

User Information

New Notifications: Multi-step Accruals at a Site, IRB Approval Received, Site Registration Approval or Change on Selected Protocols, IRB Approval Expiring in 30 Days

Online Agent Order Processing Application (OAOP)

Links are now posted to the Online Agent Order Processing Application (OAOP) for studies that Pharmaceutical Management Branch (PMB) provides agent.

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

NCI National Clinical Trials Network NRG-GY005 IRBManager Add to My Protocols

A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women with Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (COCOS)

Site Registration Documents

1	CTSU IRB Certification Form		PDF	2/5/2016
2	IRB/Regulatory Approval Transmittal Form		PDF	2/5/2016
3	Model Informed Consent - Spanish Version - Phase III	11/17/2015	Word97	3/17/2016
4	Certificate of Accuracy - Spanish Consent Translation - Phase III	11/17/2015	PDF	3/17/2016
5	Model Informed Consent Phase II	11/17/2015	Word97	2/18/2016
6	Model Informed Consent - Spanish Version - Phase II	11/17/2015	Word97	3/17/2016
7	Certificate of Accuracy - Spanish Consent Translation - Phase II	11/17/2015	PDF	3/17/2016
8	HIPAA Information Page		PDF	2/5/2016
9	PMB Online Agent Order Processing (OAOP) NOTE: Investigator Brochures for DCTD/CTEP-sponsored IND agents are accessible directly through PMB's OAOP website. IMPORTANT: Drug safety reports should be submitted per local IRB policy along with the Investigator Brochure at the time of submission for local IRB review.		WebLink	5/11/2016

Pharmacy Forms

1	PMB Online Agent Order Processing (OAOP)		WebLink	2/5/2016
2	To access the following forms please go to the CTEP Forms, Templates, and Documents page: NCI Investigational Agent Accountability Record Form NCI Transfer Investigational Agent Form NCI Return Investigational Agent Form		WebLink	2/5/2016

Imaging and Radiation Oncology Core (IROC) Credentialing Status Inquiry (CSI) Form

Home Funding Information LPO Documents Drug Safety Notification Study Agent CIRB Documents				
 NRG-BN001 <small>a National Cancer Institute program</small>		IRBManager Add to My Protocols		
Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation with Concomitant and Adjuvant Temozolomide in Patients with Newly Diagnosed Glioblastoma				
Site Registration Documents				
1	CTSU IRB Certification Form 		PDF	9/15/2015
2	IRB/Regulatory Approval Transmittal Form 		PDF	9/15/2015
3	Model Informed Consent (Amendment #1) 	8/7/2015	Word97	9/15/2015
4	Model Informed Consent - Spanish Version (Amendment #1) 	8/7/2015	Word97	11/12/2015
5	Certificate of Accuracy - Spanish Consent Translation (Amendment #1) 	10/16/2015	PDF	11/12/2015
6	HIPAA Information Page 		PDF	9/15/2015
7	Memorandum: IND Exempt for Temozolomide 		PDF	9/15/2015
8	Radiation Therapy Facility Inventory Form  NOTE: Sites that are not a member of the lead organization must have a current copy of this form on file with the CTSU Regulatory Office, or submit one indicating participation in the RPC monitoring program, prior to enrolling to this study.		PDF	9/15/2015
9	NRG-BN001 RTQA Credentialing RT Credentialing Requirements		Plain Text	9/15/2015
10	Complete or Update Your Online Electronic Facility Questionnaire (This link will take you to the IROC Houston website).		Plain Text	9/15/2015
11	IROC Credentialing Status Inquiry (CSI) Form NOTE: This study has IROC radiation/imaging credentialing requirements. The CSI form must be completed as the first step in the credentialing process.			
12	Phantom Irradiation (This link will take you to the IROC Houston website).		Plain Text	9/15/2015

Start the RT credentialing process here!

Contact Information & Questions

- CTSU Help Desk
 - CTSUcontact@westat.com
 - 1-888-823-5923

