



CTSUS UPDATES

Spring Site Operations Meeting

Today's Updates

- Delegation of Tasks Log (DTL)
- Imaging and Radiation Oncology Core (IROC) Integration



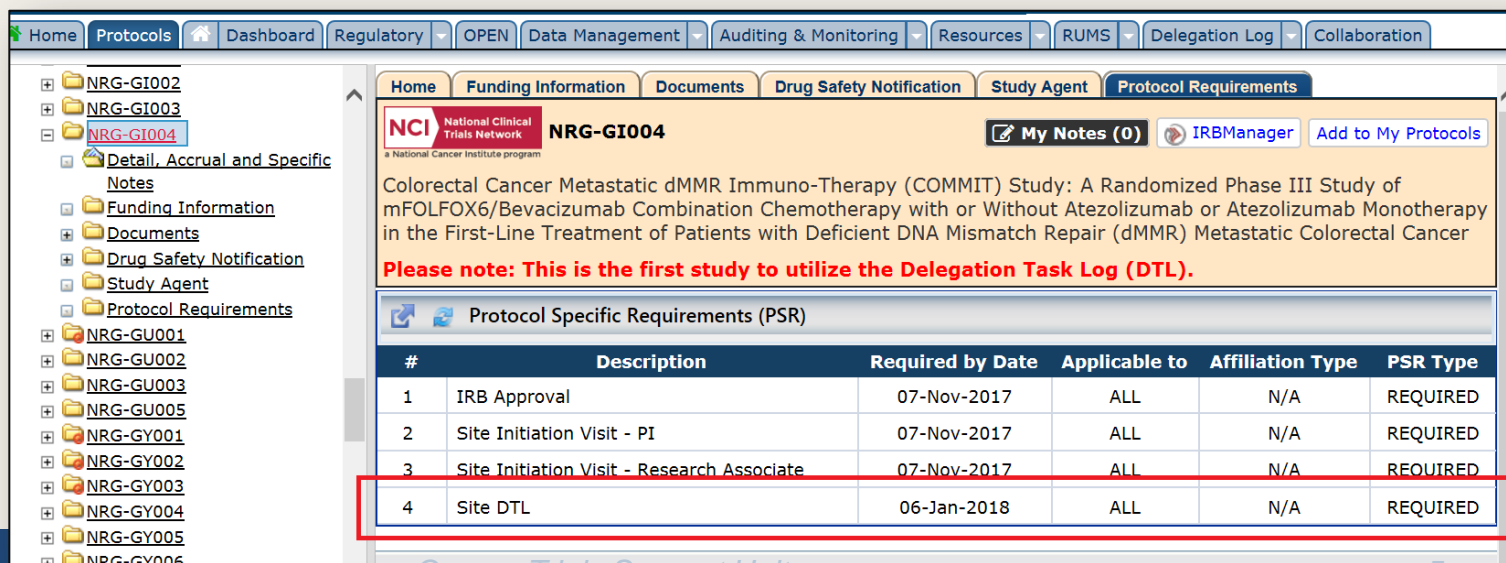
DELEGATION OF TASKS LOG

What is the Delegation of Tasks Log?

- The Delegation of Tasks Log (DTL) documents the delegation of tasks by the site Clinical Investigator (CI) to appropriately trained site staff at the clinical site for a protocol
- The DTL is required for select protocols as determined by the Cancer Therapy Evaluation Program (CTEP) or the Division of Cancer Prevention (DCP)
- For select protocols, a signed DTL is required to obtain an approved site registration and enroll subjects in OPEN

Which Studies Require a DTL?

- CTEP or DCP will determine when a study requires a DTL
- In general, required for studies under a CTEP Investigational New Drug (IND) application, and/or that support FDA registration
- Information on DTL requirements is included in the protocol webpages [See CTSU members' website → Protocols or Regulatory Tabs → Protocol Requirements subtab]
- DTL activation notices will be in Bi-Monthly Broadcasts and/or targeted broadcasts when a new DTL is activated



The screenshot shows the NCI National Clinical Trials Network website. The left sidebar lists various protocols, with NRG-GI004 selected. The main content area displays the 'Protocol Requirements' tab for NRG-GI004. The study title is 'Colorectal Cancer Metastatic dMMR Immuno-Therapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or Without Atezolizumab or Atezolizumab Monotherapy in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer'. A note states: 'Please note: This is the first study to utilize the Delegation Task Log (DTL)'. Below this, a table titled 'Protocol Specific Requirements (PSR)' lists the requirements.

#	Description	Required by Date	Applicable to	Affiliation Type	PSR Type
1	IRB Approval	07-Nov-2017	ALL	N/A	REQUIRED
2	Site Initiation Visit - PI	07-Nov-2017	ALL	N/A	REQUIRED
3	Site Initiation Visit - Research Associate	07-Nov-2017	ALL	N/A	REQUIRED
4	Site DTL	06-Jan-2018	ALL	N/A	REQUIRED

Metrics as of March

LPO	Protocol	DTL Template Activation Date	Grace Period Ends	Approved Site Registrations	Total Site DTLs	Approved Site DTLs
Alliance	A021502	15-Dec-2017	13-Feb-2018	295	418	297
Alliance	A051301	16-Jan-2018	17-Mar-2018	99	151	104
Alliance	A021602	Submitted on 21-Feb-2018		0		
COG	AEWS1221	05-Mar-2017	04-May-2018	305	9	2
E-A	EA8143	06-Feb-2018	07-Apr-2018	181	213	117
E-A	EA5142	Approved 05-Mar-2018		646		
NRG	NRG-GI004	07-Nov-2017	N/A	111	210	164
NRG	NRG-HN004	12-Dec-2017	N/A	15	77	48
PBTC	PBTC-050	Submitted on 09-Mar-2018				
PBTC	PBTC-045	Submitted on 09-Mar-2018				
SWOG	S1418	14-Feb-2018	15-Apr-2018	528	340	201
TOTALS		7 Activated 1 Approved 2 Submitted			1418	933

Initiating a DTL (1)

- 1 On the CTSU members' website, select the Delegation Log tab and click on the **New Site DTL** button

The screenshot shows the CTSU (Cancer Trials Support Unit) website interface. The top navigation bar includes the CTSU logo, a welcome message for Caroline Evan Porter, and a search bar. The main navigation menu has tabs for Home, Protocols, Dashboard, Regulatory, OPEN, Data Management, Auditing & Monitoring, Resources, RUMS, Delegation Log, and Collaboration. The Delegation Log tab is selected. Below the navigation bar, the 'Site DTL Browser' section is visible. It contains a breadcrumb trail 'Delegation Log > Site DTL Browser' and a 'New Site DTL' button highlighted with a red box. Below the button are several dropdown menus for filtering: Site (All User Sites), LPO (All user LPOs), Protocol (All viewable pro...), Protocol Status (All Protocol Statuses), and DTL Status (All DTL Statuses). A 'Go' button is next to these filters. Below the filters is a table header for the DTL Browser, with columns: #, Site, LPO, Protocol, Protocol Status, Template Revision, DTL Status, Status Reason, Last CI Approval Date, Updated Date, Updated By, and Action. The table currently shows 'No records were found that matched the criteria'.

- Any individual with an active CTEP status and on a participating roster at the site can initiate the DTL
 - Once signed by the CI, only the CI and the DTL Administrator (DTLA) can update the DTL

Initiating a DTL (2)

2 Select the site and protocol from the drop down list...

CTSUTEST > Speaking: Karen Martier | [Feedback](#) | [Public Site](#) | [Log Out](#)
Version: 6.7.6.0

My Account | CRISP | Welcome Caroline Evan Porter. Your password will expire in 8 days. You are impersonating user Audrey Haas. [Impersonate another user](#) | Search for... | Go!

Home | Protocols | Dashboard | Regulatory | OPEN | Data Management | Auditing & Monitoring | Resources | RUMS | Delegation Log | Collaboration

Site DTL Browser

Delegation Log > Site DTL Browser > Initiate Site Delegation Log

Site: Fairview Lakes Medical Center(...) Protocol: NRG-GI004 Go

Task List

#	Task	Primary	Required	Task Origin	CI Sign Required	Registration Type	Rostered	Task-Specific Training Requirements
No Tasks were found.								

3 ... and then click on the **Initiate DTL** button

Delegation Log > Site DTL Browser > Initiate Site Delegation Log

Template Information

Document Number: NRG-GI004
Document Type: Protocol
Document Title: Colorectal Cancer Metastatic dMMR Immuno-Therapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or Without Atezolizumab or Atezolizumab Monotherapy in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer
Lead Group: NRG
Template Status: Activated
Template Revision: 16-Oct-2017 03:19 PM

Site: Fairview Lakes Medical Center(...) Protocol: NRG-GI004

Task List

#	Task	Primary	Required	Task Origin	CI Sign Required	Registration Type	Rostered	Task-Specific Training Requirements
1	DTL Administrator	Yes	Yes	CTEP	Yes	IVR AP	Yes	Not Applicable
2	Clinical Investigator	Yes	Yes	CTEP	Yes	IVR	Yes	Not Applicable
3	Enrolling Person/Treating Investigator	No	Yes	CTEP	Yes	IVR	Yes	Not Applicable
4	Consenting Person	No	Yes	CTEP	Yes	IVR AP	Yes	Not Applicable
5	HP Assessments	No	Yes	CTEP	No	IVR AP	Yes	Not Applicable
6	Tox Assessment	No	Yes	CTEP	Yes	IVR AP	Yes	Not Applicable
7	Eligibility Assessment	No	Yes	CTEP	No	IVR AP	Yes	Not Applicable
8	Rave CRA	No	Yes	CTEP	No	IVR AP	Yes	Not Applicable
9	OPEN Registrar	No	Yes	CTEP	No	IVR AP	Yes	Not Applicable

Initiate DTL

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Cancer Trials Support Unit | U.S. Department of Health and Human Services | National Institutes of Health | National Cancer Institute | USA.gov

Initiating a DTL (3)

4

From the Manage Site Delegation Log screen, click on the **Assign Task** button

The screenshot shows the 'Manage Site Delegation Log' interface. On the left is a 'DTL Summary' sidebar with details for Site DTL Status (Initiated), Template Revision (31-Oct-2017 11:22 AM), Protocol Number (NRG-GI004), and Site (OH470). The main area has filters for Assignee (All), Task (All), and Status (Select Status), along with a 'View by Assignee' link. A red arrow points to the 'Assign Tasks' button. Below the filters is a table titled 'Task Assignments List for OH470, Protocol NRG-GI004' with columns: #, Assignee Name, Task Name, Status, Start Date, End Date, Status Reason, and Action. The table currently shows 'No records were found that matched the criteria'.

Site DTL Browser

Delegation Log > Site DTL Browser > Manage Site Delegation Log

DTL Summary

Site DTL Status: Initiated
Site DTL Status Reason: N/A
Template Revision: 31-Oct-2017 11:22 AM
Template Status: Activated
Protocol Number: [NRG-GI004](#)
Protocol Status: Active
Protocol Title: Colorectal Cancer Metastatic dMMR Immuno-Therapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or Without Atezolizumab or Atezolizumab Monotherapy in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer
Site: OH470
Site Name: Armes Family Cancer Center
Site Registration Status: 1 Pending
Last Updated By: 1 Dempe, Amy E.
Last Updated Date: 30-Nov-2017
Last Signed By:
Last Signed Date: N/A

Tasks Assigned

✓ No Task Assigned

Assign Task

Assignee: All Task: All Status: Select Status [View by Assignee](#) **Assign Tasks** [Help](#)

Task Assignments List for OH470, Protocol NRG-GI004

#	Assignee Name	Task Name	Status	Start Date	End Date	Status Reason	Action
No records were found that matched the criteria							

Initiating a DTL (4)

- 5** Use the drop down menus to assign tasks
- Reminders of required tasks are included on the screens

Home | Protocols | Dashboard | Regulatory | OPEN | Data Management | Auditing & Monitoring | Resources | RUMS | Delegation Log | Collaboration

Site DTL Browser

Delegation Log > Site DTL Browser > Manage Site Delegation Log > Tasks Assignment > Assign Tasks for the site OH470 and Protocol Number NRG-GI004

STEPS

1. Assign Person
2. Training Documentation
3. Review and Confirm

Previous Next Discard

Persons: Cole, Sharon (IVR-26272) Tasks: Add to Cart

Assign Tasks

#	Assignee Name
No records were found that matched the criteria	

Required Tasks Missing

Investigational Product Accountability IND Prescribing End
Enrolling Person/Treating Investigator HP Assessments OPI

☐ Check All
☐ DTL Administrator
☐ Clinical Investigator
☐ Enrolling Person/Treating Investigator
☐ Consenting Person
☐ HP Assessments
☐ Tox Assessment
☐ Eligibility Assessment
☐ Rave CRA
☐ End Point Assessment
☐ OPEN Registrar
☐ Investigational Product Accountability
☐ IND Prescribing

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U.S. Department of Health and Human Services | National Cancer Institute | USA.gov

IE 8 and above are recommended for best results

Registration Type	Task	Action
ator	DTL Administrator	Consenting Person Eligibility Assessment

External Resources

er Institute | USA.gov

Initiating a DTL (5)

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Once all tasks are assigned, click **Submit DTL**, which will trigger an e-mail to the CI to log in and sign the DTL, at this point, only the CI will be able to make changes

Home Protocols Dashboard Regulatory OPEN Data Management Auditing & Monitoring Resources RUMS Delegation Log Collaboration

Site DTL Browser

Delegation Log > Site DTL Browser > Manage Site Delegation Log

DTL Summary

Site DTL Status: Initiated

Site DTL Status Reason: N/A

Template Revision: 31-Oct-2017 11:22 AM

Template Status: Activated

Protocol Number: [NRG-GI004](#)

Protocol Status: Active

Protocol Title: Colorectal Cancer Metastatic dMMR Immuno-Therapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or Without Atezolizumab or Atezolizumab Monotherapy in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer

Site: MI013

Site Name: Saint Joseph Mercy Hospital

Site Registration Status: i Pending

Last Updated By: i Harr, Jaime

Last Updated Date: 20-Dec-2017

Last Signed By:

Last Signed Date: N/A

Tasks Assigned

- ✓ Clinical Investigator
- ✓ DTL Administrator
- ✓ Consenting Person
- ✓ Eligibility Assessment
- ✓ End Point Assessment
- ✓ Enrolling Person/Treating Investigator

Assignee **Task** **Status** [Assign Tasks](#) [View by Assignee](#) [Help](#)

Task Assignments List for MI013, Protocol NRG-GI004


#	Assignee Name	Task Name	Status	Start Date	End Date	Status Reason	Action
1	i Al Baghdadi, Tareq (IVR-49418)	Clinical Investigator	Awaiting CI Approval				i x
2	i Harr, Jaime (AP-512707)	DTL Administrator	Awaiting CI Approval				i x
3	i Porter, Shannon (AP-520657)	Consenting Person	Awaiting CI Approval				i x
4	i Al Baghdadi, Tareq (IVR-49418)	Eligibility Assessment	Awaiting CI Approval				i x
5	i Al Baghdadi, Tareq (IVR-49418)	End Point Assessment	Awaiting CI Approval				i x
6	i Beekman, Kathleen (IVR-38672)	Enrolling Person/Treating Investigator	Awaiting CI Approval				i x
7	i Al Baghdadi, Tareq (IVR-49418)	HP Assessments	Awaiting CI Approval				i x
8	i Al Baghdadi, Tareq (IVR-49418)	IND Prescribing	Awaiting CI Approval				i x
9	i Craft, Rana (AP-543603)	Investigational Product Accountability	Awaiting CI Approval				i x
10	i Aresco, Joan (AP-512538)	OPEN Registrar	Awaiting CI Approval				i x
11	i Couch, Stephanie (AP-514431)	OPEN Registrar	Awaiting CI Approval				i x
12	i Aresco, Joan (AP-512538)	Rave CRA	Awaiting CI Approval				i x
13	i Couch, Stephanie (AP-514431)	Rave CRA	Awaiting CI Approval				i x
14	i Al Baghdadi, Tareq (IVR-49418)	Tox Assessment	Awaiting CI Approval				i x

[Submit DTL](#)

Requirements for Assigning DTL Tasks

- All tasks on the DTL require the assignee to have an active CTEP registration status
- Most tasks are limited to individuals on a participating roster at the site and registered in the Registration and Credential Repository (RCR)
- While there is a core set of required tasks, optional tasks and additional required tasks may vary between studies
- The Site DTL Browser and Master Task List provide more detail on requirements for DTL assignment

Master Task List: Task Definitions

- The Master Task List of all available tasks CTEP or the LPO may decide to put on a DTL can be found using  button and dropdown located on the Site DTL Browser and Manage Site DTL screens
- Currently there are 12 tasks required by CTEP

Clinical Investigator (CI)	History and Physical (H&P) Assessments
DTL Administrator (DTLA)	IND Prescribing
Consenting Person	Investigational Product Accountability
Eligibility Assessments	OPEN Registrar
End Point Assessment	Rave CRA
Enrolling Person/Treating Investigator	Toxicity Assessment

Task Assignment Error Messages and What to Do (1)

Task Assignment Error	What to Do
CTEP Registration Status is other than Active	Person must re-register through the RCR (IVR, NPIVR, AP) or through CTEP-IAM (A)
CTEP Registration Type is not allowed to perform this task	Person must re-register through the RCR with a registration type required for the task or assign someone else to the task
Member role status is not Active or Follow-up status	Person must be at the site on a participating roster, if this is not the case, then this error will occur, request Site Administrator add person to site in RUMS
IRB number for the CI is not valid	The CI's 1572 must be updated in RCR with IRB Number associated with the site registration

Task Assignment Error Messages and What to Do (2)

Task Assignment Error	What to Do
CI does not have CTEP-IAM Account	CI must request a CTEP-IAM account., CI will not be able to sign the DTL without a CTEP-IAM account
The IRB number on the person's 1572 does not match site's IRB	For Treating / Consenting / Drug Shipment tasks the person must put the IRB number associated with the site registration on their 1572 before these tasks can be Active
Training Requirement not met. Please upload training documents.	Training documents must be uploaded before this task can be Active
This task requires the assignee to have the corresponding institutional level role	For Rave and OPEN tasks, the person must be assigned the associated RSS role before this task can become Active

Example Email Sent to CI DTL Submitted & Ready for Approval

From: CTSU Contact

Sent: Friday, December 22, 2017 11:12 AM

To: CTSUQA <CTSUQA@westat.com>; [REDACTED]

Subject: DTL for Study #E2112 Ready for CI approval

The DTL for the above referenced study is ready for CI approval. To complete review and approval of the DTL please go to <http://test-www.ctsu.org/DTL/DTLBrowser.aspx>.

For assistance please do not hesitate to contact the CTSU Help Desk at 1-888-823-5923 or ctsucontact@westat.com.

Thank you,

CTSU Operations

The content of the email notification is in the process of being updated to add step-by-step instructions

Time Requirements for Completing a DTL

- For newly activated studies, the DTL must be complete prior to obtaining an approved site registration status
- For already active studies, registered sites have 60 calendar days to complete the DTL after activation of the amendment to retain an approved site registration status
- For new versions of the DTL on a study, registered sites have 60 calendar days to complete the DTL update to retain an approved site registration status

Training Materials

Help Topics ▾

- Detailed help text is located in the help topics button on each DTL screen and can be navigated by clicking the button or using the dropdown menu
- Additional resources can be found in the Site DTL Browser > Help Topics button > DTL Resources or in Resources Tab (folder location in parentheses)
 - DTL Fact Sheet (CTSUS Operations Info)
 - DTL Webinar Recording & Slide Set (Educational Multimedia> Webinars)
 - DTL FAQs (Frequently Asked Questions)



IMAGING AND RADIATION ONCOLOGY CORE (IROC) INTEGRATION

Goals

- Update access rights to Transfer of Images and Data (TRIAD)
- Streamline the radiation (RT) and image (I) credentialing process
- Uniformly identify RT/I providers and link the providers to enrolling sites
- Enhance IROC's ability to capture RT/I providers at the site registration and patient case level

Major Integration Components

System/Integration

What it allows

IROC and CTEP



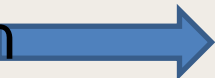
Creation of unique RT/I

IROC and CTSU



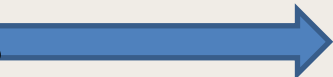
codes

Provider Application



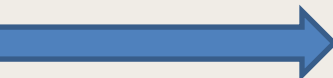
Exchange of credentialing

Roster updates



data

OPEN updates



Align enrolling sites to their
providers

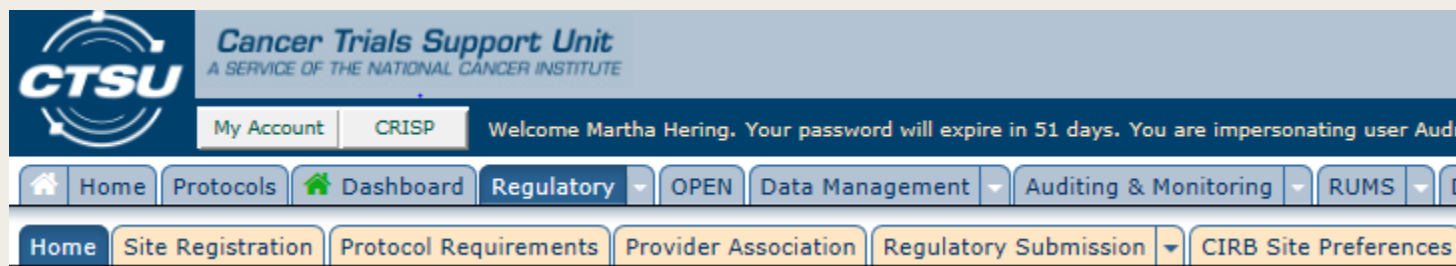
Update TRIAD access

Changes for Sites

- Align to RT/I providers
- Maintain TRIAD access on the NCTN and/or provider roster
- Be aware of process changes for submitting RT/I credentialing to the CTSU Regulatory Office
- Indicate RT/I provider in OPEN when applicable

Align to RT/I Provider

- From the Regulatory tab, access the Provider Association subtab on the CTSU website



- Follow instructions to align enrolling site to provider
 - Must have a primary role to make the update
 - Must ensure all necessary agreements and IRB coverage are in place with the provider
 - ❖ *Provider and enrolling site may be the same entity but will have different CTEP codes*

TRIAD Site User Role

- TRIAD access will be maintained on the NCTN and Provider rosters
- CTSU will migrate the TRIAD Site User role from the CTSU roster to the individual's associated NCTN roster
- Any individual on the provider roster will have access to TRIAD
- After the migration, use the Roster Update Management System (RUMS) to maintain the TRIAD Site User role and the provider roster

Submission of Credentialing Requirements

- New studies using the integration – do not require submission of credentialing e-mails to the CTSU Regulatory Office
- Credentialing requirements will be automatically exchanged between IROC and CTSU
- ❖ *IROC will still generate approval e-mails to the provider and site for your records*

Selecting RT/I Provider in OPEN

- For studies with an RT/I component, the enrolling site will need to indicate the RT provider CTEP ID in OPEN
- Possible Scenarios
 - Initial enrollment
 - Multiple providers
 - Transfers
 - Change of provider at enrollment steps

?? Questions ??

