



---

# **CTSUS UPDATES**

Fall Site Operations Meeting

# Agenda

- Delegation of Tasks Log (DTL) updates
  - Updates/Enhancements
  - Notifications
  - Best practices
  - Reminders
- General reminders



---

# **DELEGATION OF TASKS LOG (DTL)**

# Revert DTL back to Initiated

- The DTL Administrator (DTLA) can revert a DTL in Awaiting CI Approval back to Initiated status

Delegation Log > Site DTL Browser

Site: Children's Hosp... x LPO: All user LPOs Protocol: All viewable pro... Protocol Status: All Protocol Statuses DTL Status: All DTL Statuses Go

#	Site	LPO	Protocol	Protocol Status	Template Revision	DTL Status	Status Reason	Last CI Approval Date	Updated Date	Updated By	Action
1	CA161	COG	AEWS1221	Active	07-Dec-2017 02:28 PM	Awaiting CI Approval			09-Aug-2018	Salisi, Rhodeza	

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

IE 8 and above are recommended for best results

# Delete a Site DTL

## A DTL in Initiated Status can be deleted

The screenshot shows the CTSU website interface. At the top, there is a navigation bar with the CTSU logo and the text "Cancer Trials Support Unit A SERVICE OF THE NATIONAL CANCER INSTITUTE". The user is logged in as "Caroline Evan Porter" and is impersonating "Simone Williamson". The page title is "Site DTL Browser".

The main content area shows a table of Site DTLs. The table has the following columns: #, Site, LPO, Protocol, Protocol Status, Template Revision, DTL Status, Status Reason, Last CI Approval Date, Updated Date, Updated By, and Action. There are two rows of data:

#	Site	LPO	Protocol	Protocol Status	Template Revision	DTL Status	Status Reason	Last CI Approval Date	Updated Date	Updated By	Action
1	FL213	ECOG-ACRIN	EA5142	Active	21-Feb-2018 11:07 AM	Initiated			09-Aug-2018	Williamson, Simone	[Refresh] [Print] [Export] [Delete]
2	FL213	SWOG	S1605	Active	15-May-2018 10:01 AM	Approved		06-Aug-2018	06-Aug-2018	Patterson, Stephen	[Refresh] [Print] [Export] [Delete]

A yellow callout bubble with the text "Delete DTL" points to the red 'X' icon in the Action column of the first row.

# Changes for Cloning a DTL

CTSU Cancer Trials Support Unit  
A SERVICE OF THE NATIONAL CANCER INSTITUTE

Home | Contact | Feedback | Public Site | Log Out  
Version: 6.9.2.0

My Account | CRISP | Welcome Caroline Evan Porter. Your password will expire in 6 days. You are impersonating user Larkyna Keang. [Impersonate another user](#)

Search for... Go!

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

Site DTL Browser

Delegation Log > Site DTL Browser

New Site DTL

Site: All User Sites | LPO: All user LPOs | Protocol: All viewable pro... | Protocol Status: All Protocol Statuses | DTL Status: All DTL Statuses | Go | Help Topics

#	Site	LPO	Protocol	Protocol Status	Template Revision	DTL Status	Status Reason	Last CI Approval Date	Updated Date	Updated By	Action
1	MA011	COG	AEWS1221	Active	07-Dec-2017 02:28 PM	Approved		13-Apr-2018	17-Jul-2018	System	
2	MA011	ECOG-ACRIN	EA5142	Active	21-Feb-2018 11:07 AM	Approved		17-Aug-2018	17-Aug-2018	Walsh, William V.	
3	MA011	ECOG-ACRIN	EA8143	Active	24-Jan-2018 12:39 PM	Approved		22-Mar-2018	16-Aug-2018	Keang, Larkyna	
4	MA011	ALLIANCE	A051301	Active	25-Oct-2017 06:52 PM	Approved		09-Mar-2018	13-Jun-2018	Haider, Yasmin	

Contact Us | Site Map | Disclaimer | Accessibility | Viewing Files | External Resources

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

IE 8 and above are recommended for best results

DTL Cloning

## Message from CTSU Website

You have chosen to clone the site DTL for site **MA011** on protocol **EA5142**.

**Important:** Only task assignments in 'Active' or 'Awaiting CI Approval' status will be cloned.

Please select one of the following cloning options:

- Clone site DTL to a different protocol for the same site **MA011**
- Clone site DTL to a different site for the same protocol **EA5142**

Proceed

Close

Only tasks in Active or Awaiting CI Approval status will be copied when a DTL is cloned

# DTL Summary Report

**Cancer Trials Support Unit**  
A SERVICE OF THE NATIONAL CANCER INSTITUTE

Home | Contact | Feedback | Public Site | Log Out  
Version: 6.9.2.0

My Account | CRISP | Welcome Caroline Evan Porter. Your password will expire in 6 days. You are impersonating user Larkyna Keang. [Impersonate another user](#)

Search for... Go!

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

Site DTL Browser

Delegation Log > Site DTL Browser

Site: All User Sites | LPO: All user LPOs | Protocol: All viewable pro... | Protocol Status: All Protocol Statuses | DTL Status: All DTL Statuses | Go | [New Site DTL](#) | [Help Topics](#)

#	Site	LPO	Protocol	Protocol Status	Template Revision	DTL Status	Status Reason	Last CI Approval Date	Updated Date	Updated By	Action
1	MA011	COG	<a href="#">AEWS1221</a>	Active	07-Dec-2017 02:28 PM	Approved		13-Apr-2018	17-Jul-2018	System	
2	MA011	ECOG-ACRIN	<a href="#">EA5142</a>	Active	21-Feb-2018 11:07 AM	Approved		17-Aug-2018	17-Aug-2018	Walsh, William V.	
3	MA011	ECOG-ACRIN	<a href="#">EA8143</a>	Active	24-Jan-2018 12:39 PM	Approved		22-Mar-2018	16-Aug-2018	Keang, Larkyna	
4	MA011	ALLIANCE	<a href="#">A051301</a>	Active	25-Oct-2017 06:52 PM	Approved		09-Mar-2018	13-Jun-2018	Haider, Yasmin -	

Contact Us | Site Map | Disclaimer | Accessibility | Viewing Files | External Resources

[National Institutes of Health](#) | [National Cancer Institute](#) | [USA.gov](#)

recommended for best results

DTL Summary Report

DTL Summary Report				
EA8143 (A Phase 3 Randomized Study Comparing Perioperative Nivolumab Vs. Observation in Patients with Localized Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC))				
Protocol (Title)				
Inst CTEP Id (Name)				
Date Summary Report Created				
8/22/2018				
Task Assigned	Task Assignee Name	CTEP Person ID	Start Date	End Date
Clinical Investigator	Mittal, Kriti	IVR-55375	3/22/2018	5/30/2018
Clinical Investigator	Mittal, Kriti	IVR-55375	5/31/2018	On-going
DTL Administrator	Haider, Yasmin	AP-512617	N/A	N/A
DTL Administrator	Mittal, Kriti	IVR-55375	3/22/2018	5/30/2018
DTL Administrator	Mittal, Kriti	IVR-55375	5/31/2018	On-going
DTL Administrator	Keang, Larkyna	AP-559371	3/22/2018	On-going
Consenting Person	Mittal, Kriti	IVR-55375	3/22/2018	5/30/2018
Consenting Person	Walsh, William	IVR-24745	3/22/2018	7/8/2018
Consenting Person	Yates, Jennifer	IVR-618827	N/A	N/A
Consenting Person	Pasquale, Caitlin	NPIVR-557415	N/A	N/A
Consenting Person	Bathini, Venu	IVR-41084	3/22/2018	On-going
Consenting Person	Butler, Barbara	AP-533806	3/22/2018	On-going
Consenting Person	Robichaud, Ashley	AP-600531	3/22/2018	On-going
Consenting Person	Mittal, Kriti	IVR-55375	5/31/2018	On-going
Consenting Person	Walsh, William	IVR-24745	7/9/2018	On-going
Eligibility Assessment	Walsh, William	IVR-24745	3/22/2018	7/8/2018
Eligibility Assessment	Mittal, Kriti	IVR-55375	3/22/2018	5/30/2018
Eligibility Assessment	Yates, Jennifer	IVR-618827	N/A	N/A
Eligibility Assessment	Pasquale, Caitlin	NPIVR-557415	N/A	N/A
Eligibility Assessment	Walsh, William	IVR-24745	7/9/2018	On-going
Eligibility Assessment	Bathini, Venu	IVR-41084	3/22/2018	On-going
Eligibility Assessment	Mittal, Kriti	IVR-55375	5/31/2018	On-going
End Point Assessment	Walsh, William	IVR-24745	3/22/2018	7/8/2018

An Excel spreadsheet is available for sites to easily view all DTL assignments and status

# New DTL Portlet

A new portlet called 'DTLs Awaiting CI Approval' is available on the CTSU Dashboard to list those DTLs awaiting a CI's signature

The screenshot shows the CTSU Dashboard interface. The 'DTLs Awaiting CI Approval' portlet is highlighted with a red border and contains the following data:

#	Site	Protocol	Action
1	NV080	EA8143	[Folder Icon]
2	NV080	A021602	[Folder Icon]
3	NV080	NRG-GI004	[Folder Icon]
4	NV080	A021502	[Folder Icon]
5	NV080	S1418	[Folder Icon]
6	NV080	S1605	[Folder Icon]
7	NV105	NRG-GI004	[Folder Icon]
8	NV105	S1605	[Folder Icon]
9	NV105	A021502	[Folder Icon]
10	NV105	A021602	[Folder Icon]

Below the table, it shows 'Page 1 of 2' and 'Last update: 3:00:05 PM UTC'.

Other portlets visible include:

- Quick Links:** A list of 8 links to external service provider websites, including Alliance Member Website, COG Member Website, ECOG-ACRIN Portal, Medidata Portal, IRBManager Website, NCORPSYS Website, NRG Website, and SWOG Website.
- Protocol Accrual Summary at all sites:** A table showing accrual data for 6 protocols across various sites.
- Protocol Profile:** A table showing details for 7 protocols, including Protocol Number, Status, Status Date, APCD, PCD, and various checkboxes for CIRB, OPEN, RAVE, TRIAD, TSDV, DQP, CM, and DTL.



# DTL Audit History Improvements

CTSU Cancer Trials Support Unit  
A SERVICE OF THE NATIONAL CANCER INSTITUTE

Home | Contact | Feedback | Public Site | Log Out  
Version: 6.9.2.0

My Account | CRISP | Welcome Caroline Evan Porter. Your password will expire in 6 days. You are impersonating user Larkyna Keang. [Impersonate another user](#)

Search for... Go!

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

Site DTL Browser

Delegation Log > Site DTL Browser

Site: All User Sites | LPO: All user LPOs | Protocol: All viewable pro... | Protocol Status: All Protocol Statuses | DTL Status: All DTL Statuses | Go

New Site DTL | Help Topics

#	Site	LPO	Protocol	Protocol Status	Template Revision	DTL Status	Status Reason	Last CI Approval Date	Updated Date	Updated By	Action
1	MA011	COG	AEWS1221	Active	07-Dec-2017 02:28 PM	Approved		13-Apr-2018	17-Jul-2018	System	
2	MA011	ECOG-ACRIN	EAS142	Active	21-Feb-2018 11:07 AM	Approved		17-Aug-2018	17-Aug-2018	Walsh, William V.	
3	MA011	ECOG-ACRIN	EAS142	Active	24-Jan-2018 12:39 PM	Approved		22-Mar-2018	16-Aug-2018	Keang, Larkyna	
4	MA011	ECOG-ACRIN	EAS142	Active	24-Jan-2018 12:39 PM	Approved		09-Mar-2018	13-Jun-2018	Haider, Yasmin	

DTL Audit History

Site: MA011, Protocol: EAS143, Template Revision: 24-Jan-2018 12:39 PM

01-Jan-2016 - 22-Aug-2018 | Go | Reset results

Show audit history at DTL level  Show audit history at task level

#	Action Date	User	Audit	From State	To State	Action
1	16-Aug-2018 03:35:08 PM	Keang, Larkyna	User updated OPEN Registrar task to Mittal, Kriti (IVR-55375). Reason : This task requires the assignee to have the corresponding Institutional or Protocol level role at the site.	Pending	Pending	
2	16-Aug-2018 03:35:08 PM	Keang, Larkyna	User updated Rave CRA task to Mittal, Kriti (IVR-55375). Reason : This task requires the assignee to have the corresponding Institutional or Protocol level role at the site.	Pending	Pending	
3	16-Aug-2018 03:35:08 PM	Keang, Larkyna	User removed Investigational Product Accountability task from Pasquale, Caitlin (NPVR-557415).	Active	Inactive	
4	15-Aug-2018 09:25:58 AM	Keang, Larkyna	User assigned IND Prescribing task to Yates, Jennifer (IVR-618827).	Pending	Awaiting CI Approval	
5	15-Aug-2018 09:25:58 AM	Keang, Larkyna	User assigned Investigational Product Accountability task to Yates, Jennifer (IVR-618827). Reason : Task assignment does not require CI sign-off	Pending	Active	

DTL Audit History

Date Filtering

DTL Audit History

- Updated messages and information
- Added audit history for individual task assignments
- Added date filtering

# Additional DTL Updates

- Alert message will display if a task is removed that will cause the DTL to change status to Unapproved
- DTL for Canadian Sites
  - Integrated with CCTG's Roster Interface Program and Participants List Environment (RIPPLE) application
  - Canadian sites will use RIPPLE when CCTG is a study participant and holds the Clinical Trial Application (CTA).
  - All DTL information for Canadian sites will be viewable through the CTSU's DTL application

# Notifications to Sites

Description	Sent To	Frequency
DTL Status changes from Approved to Unapproved	CI & DTLAs	Once
DTL Submitted for CI Approval	CI & DTLAs	Once
DTL Tasks Requiring CI Sign-off	CI & DTLAs	Once between signings if new tasks requiring CI sign-off are Awaiting CI Approval
DTL Annual Re-Approval	CI & DTLAs	30, 14, and 1 calendar day(s) before due date.

# Best Practices

- Assign Two DTLAs
- Use caution with the clone feature
  - Remove people who are not working on the study
  - Review to make sure those working on the study are included
- Complete updates to task assignments in one sitting to minimize notifications to the CI

# Reminders (I)

- If there is no IRB approval on file, the DTL cannot be submitted for signing
- Treating / Crediting, Consenting, and Drug Shipment task assignments require the IRB Number on the person's FDA 1572 Form to match the site's IRB Approval for the protocol
- IRB Number on the CI's FDA 1572 Form must match the site's IRB approval for the protocol

# Reminders (2)

- When the CI initially signs the DTL, they are only approving the task assignments in Awaiting CI Approval status
- **Any tasks in Pending status are considered not signed-off**
- All tasks requiring CI sign-off will need CI approval before becoming Active
- Once a DTL is initially signed, tasks that do not require CI sign-off will automatically be set to an Active status assuming all task requirements have been met

# Reminders (3)

- Once a DTL is initially signed by the CI, an Active task assignment can go to Pending status if
  - Person has a CTEP registration status of ‘suspended’ or ‘relocated’
  - Person’s highest roster status on all participating rosters is suspended (i.e., other rosters statuses are withdrawn)
  - Person no longer meets the required protocol-specific training for the assigned task
- Once all task requirements are met, the task assignment will automatically change to an Active status

# Reminders (4)

- Once a DTL is initially signed by the CI, an Active task assignment can change to an Inactive status if
  - Person has a CTEP registration status other than ‘active’ or ‘suspended’ or ‘relocated’
  - Person no longer meets the minimum registration type required for the assigned task
  - Person is withdrawn from all rosters
- An Inactive task assignment **CANNOT** be moved back to Active status



# Reminders (5)

- The CTSU will notify sites when a new DTL Template revision is Activated
  - CTSU Bi-Monthly
  - Targeted Broadcast
  - Email to DTLAs & CIs (future implementation)
- DTL Template Revisions will require site DTLs to be updated (as needed) and re-signed
  - Old site DTL will change to Retiring status
  - New site DTL will automatically be created in Initiated status
    - All task assignments will be copied over from the old site DTL, if possible
- Sites will have 60 days to re-sign their DTLs

# Reminders (6)

- By signing the DTL, the Clinical Investigator is committing to the attestations provided

I agree to conduct the study in accordance with the relevant, current protocol and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64.

I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

I agree that my registration documents (FDA Form 1572, NCI Biosketch, Financial Disclosure Form) on file with the NCI's Registration and Credential Repository (RCR) will be applied to this protocol and site-specific Delegation of Tasks Log.

**AGREEMENT:** *By signing this Electronic Signature Acknowledgment Form, I attest to the accuracy and integrity of this document and agree that my electronic signature is the legally binding equivalent to my handwritten signature. Whenever I execute an electronic signature, it has the same validity and meaning as my handwritten signature. I will not, at any time in the future, repudiate the meaning of my electronic signature or claim that my electronic signature is not legally binding.*

By checking, I agree to all commitments stated above

# 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
  - DTL Fact Sheet (CTSU Operations Info)
  - DTL Assignments (Who should be assigned on the DTL and CI Responsibilities)
  - DTL Webinar Recording & Slide Set (Educational Multimedia > Webinars)
  - DTL FAQs (Frequently Asked Questions)



---

# GENERAL REMINDERS

# CTSU Roster Retirement (I)

- Why?
  - The CTSU-specific roster supported cross-group accrual and website access, and its original functions have been migrated to the NCTN and ETCTN rosters (i.e., SWOG, Alliance, LAO-TX034, etc.) therefore
  - A separate CTSU-specific roster is no longer needed and requires additional burden on the sites to maintain

# CTSU Roster Retirement (2)

- Do I lose anything? *NO*
  - Website access is controlled by an individual being added to a roster in the Regulatory Support System (RSS) and affiliations
  - Common roles (i.e., Rave-related, Registrar, and TRIAD Site User) are on the NCTN and ETCTN rosters
  - RUMS still works to add persons, person roles, and sites for all rosters previously maintained using RUMS (NCTN, ETCTN, and CIRB)
  - CTSU Bi-Monthly Broadcast receipt is controlled by a flag in RSS and can be updated via the CTSU website (under a user's My Account button in the upper left of the screen)

# CTSU Roster Retirement (3)

- Do I need to do anything?
  - If needed, assign new OPEN Read-Only role to staff that require access to OPEN to view but not conduct registrations
- Will anything else change?
  - The CTSU targeted broadcasts will go to the primary contacts at the site's affiliated rosters; this will reach a broader set of individuals
  - Access to the Patients sub-tab and the IBCSG reports will change to persons associated with the site

# Site-Protocol Principal Investigator (PI) Check

- Verify that the site-protocol PI listed on the IRB approval is active at the site on a participating roster, and by extension lists the site in the Registration and Credential Repository (RCR) profile
- Effective fall 2018
- Notifications will be sent to PIs that would fail the check prior to implementation



# ?? Questions ??

