

Managing Delegation of Tasks Logs

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Registration and Credential Repository (RCR) Update

Registration Type	Correct Counts
A	28
AP	15717
IVR	19836
NPIVR	1215
	36796

Registration and Credential Repository (RCR) ... more to come

- Enhanced RC and back-up RC functionality
- Reports (site protocol reports – with DTLs, 1572 reports)
- Review of profile details (HSP / GCP / licensing)

Delegation of Tasks Log (DTL) - What is it?

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

What Studies Require One?

- 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 on an existing study

The screenshot displays the NCI National Clinical Trials Network interface. The left sidebar shows a list of protocols, with NRG-GI004 selected. The main content area shows the 'Protocol Requirements' tab for NRG-GI004. A red box highlights the 'Site DTL' requirement in the table below.

NCI National Clinical Trials Network NRG-GI004
My Notes (0) IRBManager Add to My Protocols

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

Please note: This is the first study to utilize the Delegation Task Log (DTL).

Protocol Specific Requirements (PSR)

#	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

ALLIANCE protocols requiring a Delegation of Tasks Log

- 15 study DTLs activated
 - **A021502**: Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair
 - **A051301**: A Randomized Double-Blind Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation Versus Placebo in Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma of the Activated B-cell Subtype
 - **A021602**: Randomized, Double-Blinded Phase III Study of CABozantinib Versus Placebo IN Patients with Advanced NEuroendocrine Tumors After Progression on Everolimus (CABINET)

When does the DTL have to be Completed?

- 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

Requirements for Assigning 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 may vary between studies
- The Site DTL Browser and Master Task List provide more detail on requirements for DTL assignment

Delegation of Tasks Log – who should I add?

- **IVR (INVESTIGATOR)**

- CTEP-Sponsored treatment trials
 - M.D., D.O., international equivalent
- DCP-Sponsored trials / some CTEP non-treatment trials
 - Multiple different healthcare professionals

Delegation of Tasks Log – who should I add?

INVESTIGATOR ONLY

- Clinical Investigator
- Drug Shipment Investigator
- IND prescribing (investigational arm and SOC arms)
- Treating / Enrolling person

Delegation of Tasks Log – who should I add?

NPIVR (Non-Physician Investigator)

- Mid-level providers
 - Examples, not limited to:
 - APN
 - PA
 - PharmD
 - NP
 - MPH
 - Etc.

Delegation of Tasks Log – who should I add?

NPIVR (Non-Physician Investigator)

- Eligibility
- End point assessment
- Enrolling/Treating (CTEP non-treatment trials and some DCP studies)
- History and Physical
- Toxicity Assessment
- Agent Prescribing -- maybe
- Rave Investigator – maybe

Delegation of Tasks Log – who should I add?

AP (Associate Plus)

- CRA / RN / Pharmacist
- RAVE roles (also requires role assignment in RSS)
- NCTN/ETCTN/LAPS/LAO/Site Administrators
- Auditor
- Registrar – OPEN (also requires role assignment in RSS)

Delegation of Tasks Log – who should I add?

AP (Associate Plus)

- Delegation of Tasks Log Administrator
- Consenting
- Investigational Product Accountability
- OPEN Registrar
- RAVE CRA

Delegation of Tasks Log Update

- Email communications
 - CI and DTLA(s)
 - CI approval required tasks
 - Annual (30, 14 and 1 day prior to due date)

Delegation of Tasks Log Issues

- RCR registration suspended
 - Person will not be in LOVs for OPEN/DTL
 - Last person on a required task → DTL will change to unapproved and Site
Registration status will be set to PENDING
 - Can no longer be Site Protocol PI (IRB PI)

Delegation of Tasks Log Questions

- Staff covering multiple sites – cloning
- Clinical Investigator practicing at multiple sites – What is reasonable?
- Changes to DTL – CI signature Required?
- General DTL site navigation – CI dashboard

Delegation of Tasks Log on the Horizon

- Bulk assignment / removal
- Bulk signing
- Dashboard for CI to help navigate signing of documents
- Local tasks – still looking into this

Where can I find Help?!?

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**

Help Topics

#	Site	LPO	Protocol	Protocol Status	Template Revision	DTL Status	Status Reason	Last CI Approval Date	Update
1	CA811	ALLIANCE	A021502	Active	03-Nov-2017 02:42 PM	Retired	Template associated with this DTL is Retiring.	18-Jul-2018	31-Jul-2018
2	CA352	ALLIANCE	A021502	Active	03-Nov-2017 02:42 PM	Retired	Template associated with this DTL is Retiring.	18-Jul-2018	31-Jul-2018
3	MA004	SWOG	S1418	Active	21-May-2018 02:08 PM	Awaiting CI Approval			31-Jul-2018
4	TN209	SWOG	S1418	Active	21-May-2018 02:08 PM	Approved		31-Jul-2018	31-Jul-2018
5	KS034	ECOG-ACRIN	EA5142	Active	21-Feb-2018 11:07 AM	Approved		31-Jul-2018	31-Jul-2018
6	KS034	ALLIANCE	A021502	Active	17-Jul-2018 10:08 AM	Approved		31-Jul-2018	31-Jul-2018
7	TN209	SWOG	S1418	Active	02-Feb-2018 09:25 AM	Retired		04-May-2018	31-Jul-2018
8	TN189	SWOG	S1418	Active	02-Feb-2018 09:25 AM	Retired		04-May-2018	31-Jul-2018
9	TN141	SWOG	S1418	Active	02-Feb-2018 09:25 AM	Retired		04-May-2018	31-Jul-2018
10	NI115	SWOG	S1418	Active	21-May-2018 02:08 PM	Approved		28-Jun-2018	31-Jul-2018

- [DTL Browser Descriptions](#)
- [Overview of Site DTL Browser](#)
- [Initiating a Site DTL](#)
- [Assigning DTL Tasks](#)
- [DTL Task Wizard](#)
- [Clinical Investigator \(CI\) Sign-off Process](#)
- [DTL Resources](#)
- [Master Task Descriptions](#)
- [View available/upcoming DTLs](#)



Questions??



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