CCTG

RIPPLE TRIAL PARTICIPANTS LIST DELEGATION OF TASKS LOG (DTL) COMPONENTS USER GUIDE

Version: 1.0 2018JUL13

Canadian Cancer Trials Group

Queen's University

Kingston, ON

Canada K7L 3N6

Table of Contents

1   INTRODUCTION

The Delegation of Tasks Log (DTL) has now been implemented by the National Cancer Institute (NCI) for selected National Clinical Trials Network (NCTN) trials. The CTEP Registration & Credentialing Repository (RCR) was previously implemented for CCTG members involved in NCTN trials. With support from the US NCI, CCTG has integrated the Participants List RIPPLE environment to include the DTL requirements. NCTN Participants Lists will now involve one consistent interface to ensure compliance to all regulations and guidelines.

Canadian sites will create and manage the Participants List CCTG and DTL components directly in the CCTG Roster Interface Program and Participants List Environment (RIPPLE). Information from the DTL in RIPPLE will then be transferred directly (in "real-time") to the NCI DTL system. Information will also be transferred from the NCI DTL system back to the RIPPLE DTL and will be displayed in RIPPLE (for example, start dates or change in status related to RCR accounts). This process is referred to as **syncing** the two systems and is shown on the DTL in RIPPLE.

The Trial PL: DTL Components is a web-based utility within RIPPLE where CCTG members can:
- Define and maintain an online Trial PL: DTL Components for designated NCTN studies requiring a DTL
- Define a standard list of NCI research tasks to be part of the DTL
- Delegate research tasks based on qualifications and Registration Type
- Document the Clinical Investigator's (CI) approval of task additions and removals

The DTL components of the PL can be accessed through RIPPLE via the CCTG homepage
- Click on the ***CCTG Toolbox***
- Under ***Applications*** click on ***RIPPLE***
- Log in using your CCTG Member User ID and password
- Select ***NCI DTL Components*** from the PL of the particular trial within RIPPLE

Systems integrations and reminders are in place to ensure consistency across the Trial PL. Notifications will be sent in cases where discrepancies are noted. In addition, sites should review the Trial PL CCTG and DTL components to ensure accuracy and to ensure assignments are reflective of site processes. Further information on system features will be provided in this user guide.

This user guide provides an overview of the key functions associated with each component of the Trial PL: DTL Components
- Membership accounts
- Registration Types
- Creating, approving and managing a DTL

Additional resources are available using the 'Resource' link found on the top right corner of the RIPPLE main page. Questions regarding RIPPLE can be emailed to RIPPLE@ctg.queensu.ca.

2 ACRONYMS

A: Associate

AB: Associate Basic

AP: Associate Plus

CI*: Clinical Investigator (Equivalent to the CCTG QI)

CRA: Clinical Research Associate

CTEP: Cancer Therapy Evaluation Program

CTSU: Cancer Trials Support Unit

DCP: Division of Cancer Prevention

DTL: Delegation of Tasks Log

DTLA: Delegation of Tasks Log Administrator

IAM: Identity and Access Management Account

IVR: Investigator

LPO: Lead Protocol Organization

NCTN: National Clinical Trials Network

NCI: National Cancer Institute

NPIVR: Non-Physician Investigator

OAOP: Online Agent Order Processing

OPEN: Oncology Patient Enrollment Network

PL: Participants List

PLD: Participants List Delegate

PMB: Pharmaceutical Management Branch

QI: Qualified Investigator

RAVE: Medidata Clinical Data Management System

RCR: Registration & Credential Repository

RIPPLE: Roster Interface Program & Participants List Environment

RSS: Regulatory Support System

RUMS: Roster Update Management System (CTSU Website component)

TRIAD: Transfer of Images and Data

*The CI and QI refer to the same role BUT apply to different regulatory standards

3 MEMBERSHIP ACCOUNTS AND REGISTRATION TYPES

## 3.1 CTEP IAM Account

In order to be added to the DTL, all individuals must be registered with CTEP-IAM and maintain an *active registration annually*. In addition, individuals whose registration type is Investigator (IVR), Non-Physician Investigator (NPIVR) and Associate Plus (AP) must register and maintain an *active status* in the Registration and Credentialing Repository (RCR), which was released in July 2017.
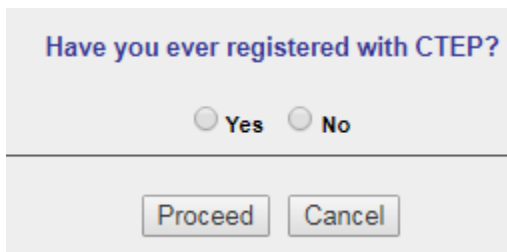
3.1.1 CTEP Identity and Access Management (IAM)

All participants who will be assigned tasks on the Trial PL: DTL Components require an active CTEP-IAM account. This account includes a CTEP user ID. To obtain and manage a CTEP-IAM account go to https://ctepcore.nci.nih.gov/iam

- Select *Request New Account* under User Account Maintenance
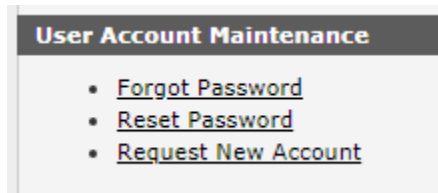
- Under Have you ever registered with CTEP? select *No* and *Proceed*

- Complete and submit the new account request
- A CTEP Identity and Access Management, New Account Request email will be sent. **Note: It can take up to 2 business days to process the account request.**
- Once approved a CTEP Identity and Access Management, Account Approved email will be sent
- The temporary password must be changed and answer(s) provided for security question(s)
- Once this is complete a CTEP Identity and Access Management, Account Activated notification will be sent
- The CTEP Person ID is assigned

3.2 Registration Types

There are 5 different Registration Types relevant to the DTL . They are:

1. Investigator (IVR)
2. Non-Physician Investigator (NPIVR)
3. Associate Plus (AP)
4. Associate (A)
5. Associate Basic (AB)

3.2.1 Investigator (IVR)

The investigator type is equivalent to the CCTG QI and includes those with an MD, DO, or international equivalent. The investigator registration type covers the following:

- Protocol PI for CTEP or DCP-sponsored protocols (START)
- Site-Protocol PI for CTEP or DCP-sponsored studies (RSS)
- Consenting or Enrolling investigator for CTEP or DCP-sponsored studies (OPEN)
- Drug Shipment investigator for CTEP-sponsored protocols
- Site Investigator for CTEP or DCP-sponsored studies (RAVE)

3.2.2 Non-Physician Investigator (NPIVR)

The Non-Physician Investigator includes advanced practice providers (e.g., NP or PA) or graduate level researchers (e.g., PhD). The NPIVR can be the protocol PI for select protocols. These protocols will be flagged by the sponsor as **NPIVR eligible as Protocol PI**

Degrees that might be expected to register as an NPIVR:

- NP (Nurse Practitioner)
- ONP (Oncology Nurse Practitioner)
- APRN (Advanced Practice Registered Nurse)
- CNS (Clinical Nurse Specialist)
- MSN (Master of Science in Nursing)
- DNP (Doctor of Nursing Practice)
- DNS (Doctor of Nursing Science)
- PA (Physician Assistant)
- PhD (Doctor of Philosophy)
- EdD (Doctor of Education)
- ScD (Doctor of Science)
- DrPH (Doctor of Public Health)
- MPH (Master of Public Health)
- PharmD (Doctor of Pharmacy)
- DPT (Doctor of Physical Therapy)

An NPIVR can be the **enrolling** investigator for select studies. They can also be the consenting person for CTEP sponsored protocols.

NOTE: An NPIVR cannot **order** study agent or be a drug shipment investigator and cannot **prescribe** study agents on CTEP-sponsored protocols.

- **Ordering** is defined as entering a request for the shipment of a CTEP investigational agent for a specific investigator on a specific protocol using PMB's OAOP application.
- **Prescribing** is defined as writing an order for a specific patient (e.g., your doctor gives you a prescription for Amoxicillin 250mg and tells you to take one capsule four times a day for 7 days OR an oncologist writes an order in the patient's chart for 1000mg of chemo agent X to be administered IV over one hour).

- **Protocol directed therapy** is defined as any *treatment* involving CTEP investigational agents or commercial agents, specified by the protocol.
- NPIVRs may NOT *order* a CTEP IND agent from PMB or *prescribe protocol directed therapy* for patients on CTEP-sponsored clinical trials.

3.2.3 Associate Plus (AP)

The Associate Plus covers clinical site staff (e.g., RN or CRA) with data entry access to CTSU applications (e.g., RUMS, OPEN, RAVE, TRIAD).

3.2.4 Associate (A)

Associates are other clinical site staff involved in the conduct of NCI-supported research. This can include:

- Administrative roles (RSS / NCI CIRB / TRIAD)
- CTSU website access
- Shipping Designee (OAOP)
- Ordering Designee (OAOP)
- Registration Coordinator (RCR)
- RAVE Read-Only (RAVE)

3.2.5 Associate Basic (AB)

Associate Basic are individuals (e.g., pharmaceutical company employees) with limited access to NCI-supported systems. This includes personnel who need to register; but who *cannot* be granted system or web access. It can include the following:
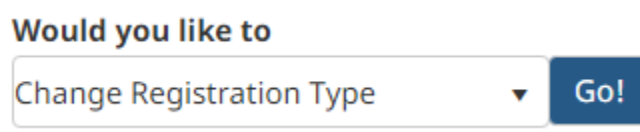
- Administrative roster (RSS)
- Biospecimen protocol PI (START)
- Biospecimen proposal PI (NCI NAVIGATOR)

3.3 CTEP Registration and Credentialing Repository (RCR)

Individuals who are an IVR, NPIVR or AP are also required to register in RCR and meet the criteria for their registration type.

To obtain an RCR account go to https://ctepcore.nci.nih.gov/rcr and complete the following steps:

- Enter your IAM Username and Password
- To change your Registration Type, select *Change Registration Type* from the *Would you like to* menu

Would you like to

| Change Registration Type ▼ | Go! |

- To begin registering as your selected Registration Type, select **Update FDA Form 1572** (for IVR or NPIVR) or **Update NCI Biosketch** (for AP) from the **Would you like to** menu
- Follow the onscreen prompts to complete your profile, generate and sign your documents, and submit your registration packet to CTEP

Documentation Required	IVR	NPIVR	AP	A	AB
FDA Form 1572	✓	✓			
Financial Disclosure Form	✓	✓	✓		
NCI Biosketch (education, training, employment, certification, and license)	✓	✓	✓		
HSP/GCP Training	✓	✓	✓		
Agent Shipment Form (if applicable)	✓				
CV (optional)	✓	✓	✓		

This RCR account must have an *active* status throughout the course of the trial in order to maintain an *active* status for each task assignment. This includes ensuring all credentialing is kept up to date and that the annual registration is completed.

4   STUDY DTL TEMPLATES

4.1   What is the study DTL template?

- The study DTL template outlines the task assignments/requirements for each study that must be completed and maintained by each site in order to participate on the study
- There are 12 mandatory tasks that must be on each study DTL template as well as several optional tasks
- The Lead Protocol Organization (LPO) selects any additional optional tasks to be added to the DTL for that specific study (if any), in addition to the mandatory tasks
- CTEP then reviews the proposed DTL template for a trial and ultimately approves it
- This then becomes the study DTL template that must be completed by each site on the study
- The study DTL template can be revised by the LPO over the course of the study which then requires each site DTL to be updated
- The study DTL template can be located on the NCI DTL components tab of the PL in RIPPLE
- The DTL template has a version date that is displayed (Template Revision date) as well as a Template Status
    - Approved (new but not yet available for sites to create)
    - Activated (available for sites to create their site DTL)
    - Retiring (being replaced with a revised template)
    - Retired (version has been replaced with a new template for sites)
- The information entered and managed in RIPPLE for each site is sent to the NCI US DTL.

4.2   RIPPLE/NCI DTL Sync Status

DTL information entered in the RIPPLE system will be sent to the NCI DTL (e.g. task assignment additions and removals). In turn, information from the NCI DTL will be transferred to the RIPPLE DTL components (e.g. task start date or status).

This process of transferring information between RIPPLE and the NCI DTL to ensure the data is consistent is called **syncing**. The sync status is displayed on the DTL in RIPPLE on the top right hand side bar.

Sync status options are:

RIPPLE/NCI DTL Sync Status	Colour	Meaning
The RIPPLE DTL is On Hold, it has not been approved and submitted to NCI yet.	Red	RIPPLE DTL has not been transferred to the NCI DTL; CI has not approved the RIPPLE DTL
The RIPPLE DTL has synced with the NCI DTL.	Green	RIPPLE DTL has not been updated since last transfer or last CI approval is on/after last transfer or there are no tasks requiring CI approval
RIPPLE/NCI DTL out of sync. There are unapproved changes to the RIPPLE DTL.	Red	RIPPLE DTL has been updated since the last CI approval; RIPPLE DTL tasks require CI approval

The RIPPLE DTL has synced with the NCI DTL with issues. Please attend to the Statuses and Status Reasons on the page for more information.	Red	RIPPLE DTL has not been update since last transfer; Site DTL Status is something other than Approved
There was an issue. Please attend to the Status and Status Reasons on the page or contact support.	Red	A case other than the above

4.3 DTL Site Template Status

The DTL has an overall status which influences participation on the trial. The DTL status for the site will be displayed in RIPPLE on the DTL (top right hand side bar) after the initial DTL created by the site has been transferred to the NCI DTL (until the initial transfer the DTL Site template status will not be visible).

The Site DTL Status options include:

DTL Status	Description
Initiated	Initial or revised DTL template which has not yet been completed by the site
Awaiting CI Approval	The DTL requires CI Approval
Approved	All mandatory tasks on the study template are assigned, all tasks have met their credentialing/training criteria, all tasks have been approved by the CI and their status is "Active"
Unapproved	All criteria for the DTL have not yet been met
Retiring	A version of the site DTL which is being replaced by a new "Initiated" DTL, but the new DTL has not yet been completed and approved
Retired	A previous version of the site DTL which has been replaced by a revised version of the site DTL

The status of the site DTL can change over the course of the trial (for example if an individual is removed from the DTL components and they are the only individual assigned to a mandatory task, this mandatory task is no longer assigned and "active" on the DTL).

DTL Status	Impact on Study Participation
Approved	• Required for local activation of the site • Required for active status of the site in RSS (initially and throughout trial) • Permits access to OPEN, EDC Rave, drug supply

	• Required to perform study enrollments
Unapproved	• Site registration status in RSS no longer active. • Enrollments not permitted
Initiated	When the initial DTL status = initiated • Site registration status not active • Access to systems (e.g. OPEN, Rave) restricted • Enrollments not permitted When the revised DTL template status = initiated • Current (retiring) DTL will still be effective and will permit continued access to systems for the duration of the 60 day grace period to have the initiated/new DTL template completed and approved • After 60 day grace period passed, if DTL status is not "approved", site registration is no longer active, access to systems may be restricted, enrollments are not permitted

If the status of the DTL template changes from **approved** to **unapproved** over the course of the trial, a notification will be sent to the QI/CI and the DTLA(s) outlining the reason for the status change for immediate resolution

4.4 **Study DTL Template Permissions**

Who has the ability to initiate, make changes to, or approve the DTL?

- **Initiate the DTL:** Any member from the site in RIPPLE
- **Modify the DTL after initial CI approval:** Any individual assigned to the DTLA task (1-2 permitted per site) or the QI/CI. Modification can be adding, removing, cancelling or replacing tasks
- **Approve the DTL:** Only the individual who has been assigned the Clinical Investigator (CI) task. This should always be the same as the QI.

5 DTL Components

5.1 Individuals Assigned to the DTL

An individual can only be assigned to the DTL if they:

- Have an **active** CTEP registration status

  AND one of the following:

- Have been added to the CCTG components of the PL in RIPPLE and have met all of the credentialing/training requirements checked by CCTG for that trial

  OR

- Are the Remote Roster Administrator (RRA) or Participant List Administrator (PLA) for that trial – this individual can only be assigned the Delegation Task Log Administrator (DTLA) task unless they are also on the PL

5.2 Credentialing/Training Requirements for DTL Additions

All credentialing/training requirements possible are checked when the individual is added to the CCTG components of the trial PL and must be passed prior to adding the individual to the DTL components.

However, there are additional credentialing/training requirements that must be checked when the DTL information is transferred from RIPPLE to the NCI DTL. This happens once the task assignments have been added, there are no outstanding credentialing/training elements outstanding from the RIPPLE checks, and the CI has approved the addition. The addition and approval information is then transferred from RIPPLE to the NCI DTL and processed.

If there are any credentialing/training issues identified at that time, this information is then transferred back to the RIPPLE system and will be displayed on the DTL components screen in RIPPLE and a notification will be sent to the participant of the outstanding requirement.

Once the requirement has been addressed, the status of the task will either change to **active** or **awaiting CI approval** depending on the task and issue.

5.3 DTL Task Assignments

There are 12 mandatory tasks on each study DTL. Additional tasks may be added to the study DTL template by the LPO.

Tasks can only be assigned to individuals who have met the minimum registration type requirement for that task (e.g. AP, NPIVR, IVR)

- Some tasks (e.g. OPEN registrar, Rave CRA, Rave Investigator) require the individual to also have the appropriate institutional role (Registrar, Rave CRA, Site investigator) assigned in the Regulatory Support System (RSS) in order to be active

- This assignment in RSS is managed by CCTG and a notification will be sent to CCTG roster office if the task is assigned on the DTL for an individual who does not have the correct institutional role in RSS for resolution
- There are a maximum number of individuals that can be assigned some tasks
  - DTLA = maximum 2 people
  - CI = maximum 1 person

The QI on the CCTG components of the PL must be assigned the CI task on the DTL components

Please refer to Appendix 1 (RCR Types and DTL Tasks) for further information.

5.4 DTL Task Assignment Status

Each task assignment for each individual has one of 5 statuses:

Task Status	Meaning
New	Task has been added but not yet had credentialing checked or CI approval
Active	All credentialing criteria met (from both CCTG and NCI perspective) and CI approval received. Individual can perform this task and has access to all relevant systems
Awaiting CI Approval	All credentialing criteria met from CCTG perspective but CI approval not yet received **NOTE:** a task status may revert to **awaiting CI approval** if a task status was changed to **pending** due to an NCI credentialing issue and requires re-approval by the CI once resolved
Inactive	This task assignment for this individual has been removed (either because it was removed by the DTLA/CI or because of a roster issue in which case it may also have been reassigned as a new record with a **pending** status). A task is assigned an **inactive** status if their registration status is withdrawn
Pending	Task assignment has been added but credentialing has not yet been met or was met but is no longer met (e.g. if CTEP registration status was suspended)

- The status of a task assignment may change over the course of a trial (e.g. an **active** task assignment may change to **pending** if the individual's CTEP annual registration was not completed)
- An individual should only perform a task when the status is **active**
- Where applicable a status reason is provided to provide further information (e.g. if an issue is required to be resolved)

5.5 DTL Start and End Dates

Start and end dates are *not* selected by the site. These dates are assigned by the NCI DTL and are displayed in RIPPLE on the DTL components page beside each task.

- A start date is assigned by the NCI DTL after the task assignment and QI/CI approval has been transferred to the NCI DTL and credentialing/training requirements have been met
- An end date is assigned by the NCI DTL after the task removal and QI/CI approval has been transferred to the NCI DTL
- An end date may also be assigned by the NCI DTL if a task that was **active** no longer meets the credentialing/training requirements – in this case the task assignment is automatically changed to **inactive**, an end date is assigned and a new task assignment record may be added with a **pending** status

5.6 DTL QI/CI Approval

All task additions and removals on the DTL components of the trial PL in RIPPLE must be approved by the QI/CI.

- When a task assignment is added, removed or replaced and is ready for QI/CI approval, the CI approval page displays the current DTL with the new changes identified
- When the CI approval is completed, the entire DTL is approved
- This action assigns an initial approval date to the new tasks that have been added, removed or replaced AND a new QI/CI approval date for all existing task assignments on that DTL
- This approval (or re-approval) date is transferred to the NCI DTL for each task on the DTL
- The initial approval date and most recent QI/CI re-approval date is stored in the CCTG database

5.7 Annual Re-approval of the DTL

The NCI DTL system requires the DTL to be **approved annually** by the QI/CI

- As the QI/CI approves each task assignment on the DTL components of the PL every time there is a change to the DTL, the QI/CI approval date for each task is updated
- As a result, the anniversary date for re-signing the DTL tasks is reset from this new approval date with each approval.
- If there has not been a QI/CI approval of the DTL components in a year, reminders will be sent to the QI/CI that annual re-approval of the DTL is required 30, 14 and 1 day(s) before the annual deadline
- If the annual re-approval is not completed by the deadline, the status of the DTL will change to **unapproved** and the site registration status will change to **inactive** and enrollments will not be permitted

6 Creating and Approving the Initial DTL

6.1 When Can a Site DTL Be Initiated?

The site DTL can be initiated at any time providing the site is eligible to participate on that study

6.2 When Can An Initial Site DTL Be Approved?

- The site DTL must have all mandatory tasks assigned and all credentialing/training criteria met for each individual assignment
- The site DTL cannot be approved until CCTG has received the initial ethics approval for that trial for that site and uploaded it to the CTSU portal along with the name of the QI that is active on the CCTG components of the PL in RIPPLE
- Once the ethics approval has been reviewed by CTEP and the site is registered for that trial in RSS (approximately 3-7 days unless it has been identified as urgent due to a pending study participant), a notification will be sent to the site that the DTL can be approved by the QI/CI
- **Note:** Once all mandatory tasks have been assigned and the QI/CI has approved the initial DTL components in RIPPLE the information is transferred to the NCI DTL – if credentialing checks are not passed for one or more mandatory task assignments on the initial DTL re-approval of the initial DTL is required after the credentialing issues have been resolved

6.3 Process to Initiate a New Site DTL

Reminder: To initiate a new site DTL, the CCTG components of the Participants List (PL) must first be created for the trial at your centre (mandatory roles assigned and PL saved). Please refer to section 7 of the RIPPLE User Guide for step-by-step instructions on creating and approving a new PL.

- Select *Home* to go to the RIPPLE home page
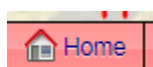
- Locate the applicable trial by selecting the disease site from the tabs and choosing the appropriate trial.
    - **Note:** you can only continue if the trial appears under the Participating Trials - View Participants List section. If the trial appears under New Trials - Create Participants List then a PL is not yet created
- The trial PL page will appear
- At the top of the page select *NCI DTL Components* to switch to the DTL portion of the PL
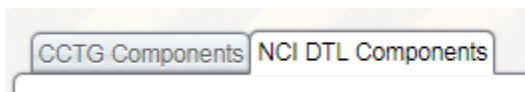
- Select *Assign Tasks*
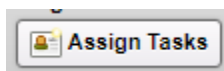
- Select a person. (Only individuals with CTEP Registration Status = Active who have met all credentialing requirements can be selected)
    - **Note:** As soon as a QI is added to a Participants List that is saved, this individual is automatically assigned the Clinical Investigator task on the DTL components of the PL
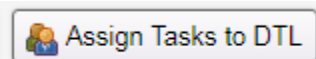

- Individuals can only be added to the DTL if they have been added to the CCTG components of PL and have met the credentialing requirements or they are the RRA or PLA on that trial for that site
- Select one or more tasks for that person. Only tasks that are valid for that individual's registration type will appear. DTL Template rules will be enforced on task assignments (only 1 CI, 1-2 DTL Admins etc.)
    - The RRA or PLA can only be assigned the DTLA task if they are also on the PL
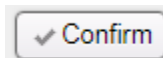- Select **Add to List**
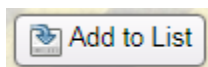
- Assigned tasks now appear in the Task Assignments List including Assignee Name, CTEP ID, Registration Type
- Each assigned task appears as a button with a remove option
- Remove button appears under Action to remove the entire Assignee

- Repeat these actions to assign tasks to various centre personnel
- Once all desired tasks are assigned select **Assign Tasks to the DTL**

- Assign Tasks confirmation message **You are about to assign the persons and tasks listed on this page to the DTL. Are you sure?** appears
- Select **Confirm**

- Task assignments are submitted and the Trial Participants List: NCI DTL Components page appears
- Assigned tasks appear in the Task Assignments List along with the Clinical Investigator. Assignee Name appears as Lastname, Firstname (Type - CTEP ID). Task Name appears. Status is 'New' with no Start Date, End Date, and Status Reason. Undo button appears for all tasks.
- RIPPLE/NCI DTL Sync Status is **The RIPPLE DTL is On Hold; it has not been approved and submitted to NCI yet.**
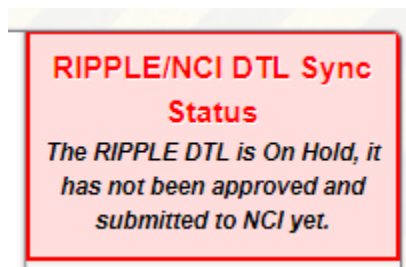
6.4 Process to Approve a New Site DTL

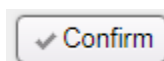**Reminder:** This can only be done by the QI/CI

- Sign in to your RIPPLE Account (or access the link in the email notification of pending CI approvals)
- There will be a notification at the top left indicating that there are DTL changes to approve
- Select *x number of DTL changes to approve*

CI: 19 DTL changes to approve.

- Select *Approve DTL*

Approve DTL

- The DTL Attestation **You are about to record your attestation for additions & removals to the DTL, as well as reapprove the existing DTL...** will appear
- Select *Confirm* to approve

✓ Confirm

- Task approval is submitted and the Trial Participants List: NCI DTL Components page appears
- Task Assignment List shows Active tasks
- RIPPLE/NCI DTL Sync Status is **The RIPPLE DTL has synced with the NCI DTL.**

RIPPLE/NCI DTL Sync
Status
The RIPPLE DTL has synced
with the NCI DTL.
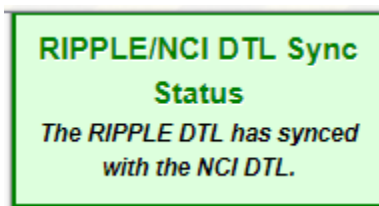
- Site DTL Status is Approved

Note: If credentialing checks done by the NCI DTL are not passed for one or more task assignments (for example an individual's registration status has changed to suspended) on the initial DTL, re-approval of the initial DTL is required after the credentialing issues have been resolved

# 7 Managing the DTL Components of the PL After the Initial DTL Is Approved

7.1 Assigning Additional DTL tasks After the Initial DTL Has Been Approved

**Reminder:** This can only be done by the individual assigned to the CI or DTL administrator (DTLA) tasks

- Select *Home* to go to the RIPPLE home page.

- Locate the applicable trial by selecting the disease site from the tabs and choosing the appropriate trial.
- The trial PL page will appear
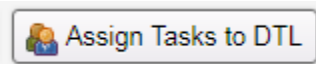- At the top of the page select *NCI DTL Components* to switch to the DTL portion of the PL
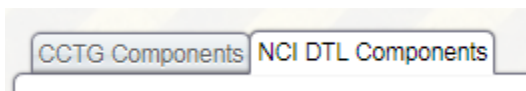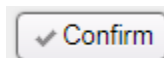

- Select *Assign Tasks*
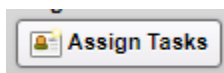
- Select a person. (Only individuals with CTEP Registration Status = Active who have met all credentialing requirements can be selected)
- Select one or more tasks for that person. Only tasks that are valid for that individual's registration type will appear. DTL Template rules will be enforced on task assignment (only 1 CI, 1-2 DTL Admins etc.)
- Select *Add to List*
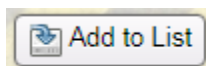
- Assigned tasks now appear in the Task Assignments List including Assignee Name, CTEP ID, Registration Type
- Each assigned task appears as a button with a remove option
- Remove button appears under Action to remove the entire Assignee
- Repeat these actions to assign tasks to various centre personnel
- Once all desired tasks are assigned select *Assign Tasks to the DTL*

- Assign Tasks confirmation message **You are about to assign the persons and tasks listed on this page to the DTL. Are you sure?** appears
- Select *Confirm*

- Task assignments are submitted and the Trial Participants List: NCI DTL Components page appears
- Task is assigned and Status is New
- Status Reason is **Awaiting CI approval and submission to the DTL**

Status Reason

Awaiting CI approval and submission to the DTL

- Undo button appears under Action
- RIPPLE/NCI DTL Sync Status is **RIPPLE/NCI DTL out of sync. There are unapproved changes to the RIPPLE DTL.**
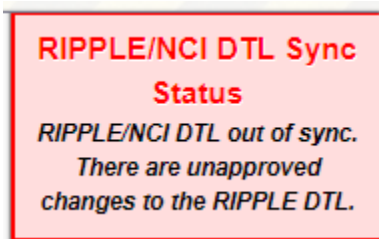
RIPPLE/NCI DTL Sync
Status
RIPPLE/NCI DTL out of sync. There are unapproved changes to the RIPPLE DTL.
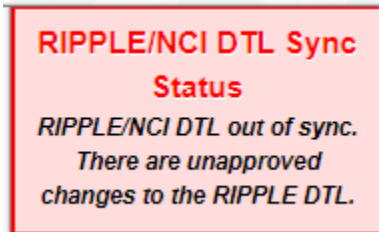
7.2 Approving DTL tasks After the Initial DTL Has Been Approved

Reminder: This can only be done by the QI/CI

- Sign in to your RIPPLE Account
- There will be a notification at the top left indicating that there are DTL changes to approve
- Select *x number of DTL changes to approve*

CI: 19 DTL changes to approve.

- Task Assignment List has all task assignments (inactive tasks are hidden)
- Assigned tasks to be approved are at the top of the task list with Status: New, Status Reason: Awaiting CI approval and submission to the DTL, and Undo button under Action
- RIPPLE/NCI DTL Sync Status is **RIPPLE/NCI DTL out of sync. There are unapproved changes to the RIPPLE DTL.**

RIPPLE/NCI DTL Sync
Status
RIPPLE/NCI DTL out of sync. There are unapproved changes to the RIPPLE DTL.

- Select *Approve DTL*

Approve DTL

- The DTL Attestation **You are about to record your attestation for additions & removals to the DTL, as well as reapprove the existing DTL...** will appear
- Select *Confirm* to approve

✓ Confirm
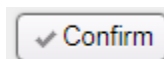
- Task approval is submitted and the Trial Participants List: NCI DTL Components page appears
- Task Assignment List shows Active tasks;
- RIPPLE/NCI DTL Sync Status is **The RIPPLE DTL has synced with the NCI DTL**.

RIPPLE/NCI DTL Sync Status
The RIPPLE DTL has synced with the NCI DTL.

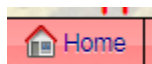- Site DTL Status is Approved

7.3 Removing DTL tasks After the Initial DTL Has Been Approved

Reminder: This can only be done by individuals assigned to the CI or DTL administrator tasks. ****This does not include the Clinical Investigator Task****

- Select *Home* to go to the RIPPLE home page.

- Locate the applicable trial by selecting the disease site from the tabs and choosing the appropriate trial.
- The trial PL page will appear
- At the top of the page select *NCI DTL Components* to switch to the DTL portion of the PL
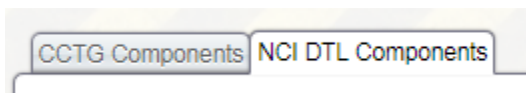
- Select *Remove* for the person and the task you wish to remove

- Remove Task Confirmation **You are about to remove the following task assignment from the RIPPLE DTL.** appears
- Select *Confirm*
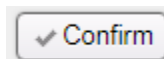
- Task is removed
- Task removal message **Task removal complete in RIPPLE, the CI must Approve the new state of the RIPPLE DTL before the changes are synced with the NCI DTL** appears
- Status Reason is **This task has been removed, and is pending Approval of the removal by the CI.**
- Undo button appears under Action (This can be used is a task was removed in error)
- RIPPLE/NCI DTL Sync Status is **RIPPLE/NCI DTL out of sync. There are unapproved changes to the RIPPLE DTL.**

RIPPLE/NCI DTL Sync Status
RIPPLE/NCI DTL out of sync. There are unapproved changes to the RIPPLE DTL.

7.4 Changing the Clinical Investigator Task After the Initial DTL Has Been Approved

The Clinical Investigator task assignment can only be **replaced** not **removed**. Follow the same process as removing a DTL task as described above however:
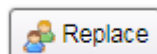
- Select *replace* for the person assigned to the CI task

  [Replace]

- Select the individual from the drop-down who will now be assigned the CI task

Note: Only an individual on the CCTG components of the PL that has been assigned the role of QI can be assigned this task

7.5 Approving Removal or Replacement of DTL tasks After the Initial DTL Has Been Approved

Reminder: This can only be done by the CI

- Sign in to your RIPPLE Account
- There will be a notification at the top left indicating that there are DTL changes to approve
- Select *x number of DTL changes to approve*

  CI: 19 DTL changes to approve.

- Task Assignment List has all task assignments (inactive tasks are hidden);
- Task removals that need to be approved are at the top of the task list with Status Reason **This task has been removed, and is pending Approval of the removal by the CI**.
- RIPPLE/NCI DTL Sync Status is **RIPPLE/NCI DTL out of sync. There are unapproved changes to the RIPPLE DTL.**

RIPPLE/NCI DTL Sync Status
RIPPLE/NCI DTL out of sync. There are unapproved changes to the RIPPLE DTL.

- Select *Approve DTL*

- Displays DTL Attestation **You are about to record your attestation for additions & removals to the DTL, as well as reapprove the existing DTL...** appears
- Select *Confirm*
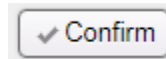
- Task approval is submitted for the removals
- Trial Participants List: NCI DTL Components page appears;
- Task Assignment List will show a Status which depends on the task removed/approved
- RIPPLE/NCI DTL Sync Status is **The RIPPLE DTL has synced with the NCI DTL.**
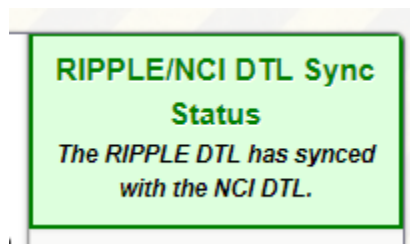
- Tasks Assigned shows all tasks assigned
- To see all removed tasks select **Include removed tasks**
- Removed tasks appear with Status Inactive and their End Date

Note: If the CI task is being replaced, the approval of the replacement must be done by the incoming CI

8 Impact of Changes in DTL Individual Task Status

The data that is entered in the DTL components of RIPPLE is transferred to the NCI DTL. In addition, information is sent to RIPPLE by the NCI DTL including start and end dates, new template revisions, changes in status of the DTL and individual task assignments.

Over the course of the trial, the credentialing for an individual may change from requirements met to requirements not met. For example, if an individual's CTEP registration status is no longer **active** as the annual renewal was not completed. In this case, the following would happen:

- The relevant task assignments for this individual would be changed to **inactive** and an end date would be populated by the DTL for each task
    - If the individual's registration has been withdrawn, a new record is not created
- For other issues, duplicate task assignments for this individual would be created with a task status of **pending** as credentialing requirements are not met (The status reason will identify the issue)
- As the individual's task assignments are now **pending** their access to some systems will be restricted (for example read only access in OPEN) and they should not be performing any tasks which are not active
- If the participant is the only individual assigned to a mandatory task, the overall status of the DTL will also be changed to **unapproved** – this means:
    - Site registration status is no longer active and enrollments are no longer permitted
    - Other individuals on the DTL remain compliant and therefore their task assignments remain **active** and their access to systems is not affected
    - New task additions and approvals will not be processed until either the individual's credentialing requirements are met OR another individual who meets the credentialing requirements is assigned that mandatory task(s)
- If the participant is not the only individual assigned to mandatory tasks, the overall status of the DTL will remain as **approved** and the issue will only be at the level of the individual task assignments
- A notification would be sent by CTEP to the individual of the credentialing issue (for example account suspended)
- A notification that the task is now **inactive** would be sent by RIPPLE to the affected individual
- If the change causes the overall DTL status to be unapproved, a notification would be sent to the QI/CI and DTLA(s) of the status change and the reason
- From the NCI DTL perspective, all task additions do not require QI/CI approval, therefore if the credentialing issue is resolved (for example CTEP registration status is now active) there are various scenarios:
    a. The task assignment will automatically change to **active** and a start date will be populated if NCI DTL does not require QI/CI approval.
        i. CCTG requires QI/CI approval of all additions and removals therefore the task addition will be sent for QI/CI approval – the task status will be **active** however the status reason will indicate QI/CI re-approval of the task is required

        OR

    b. The task assignment will change to **awaiting CI approval** if it is a task that the NCI DTL requires QI/CI approval and will be sent for QI/CI approval – once this is obtained the task status will change to **active** and a start date will be populated
- As the NCI DTL does not require removals to be QI/CI approved, the task entry that was automatically changed to **inactive** by the system and an end date was populated will still require QICI approval (status reason will show QI/CI approval is required)
- Once all mandatory tasks have at least one individual with an **active** status, the overall DTL status will change back to **approved** which will in turn permit enrollments to resume on the trial

9 Consistency Across CCTG and DTL components

CCTG systems provide a framework to ensure consistency across the Participants List including RIPPLE and DTL components. RIPPLE has a mandatory standard list of delegated duties. The DTL similarly has a mandatory standard list of delegated tasks in addition to optional tasks that may be selected by the LPO. There are systems integrations in place to support consistency which include:

- Direct mapping of Qualified Investigator (CCTG) to Clinical Investigator (DTL). After initial approval, the QI/CI can be replaced but not removed.
- Notifications sent to the QI/CI and DTLA(s) of possible discrepancies between the CCTG and DTL components of the trial PL.
- In addition to systems efficiencies, CCTG also recommends that sites review the Participants List (RIPPLE and DTL components) to ensure they are accurate and reflective of site processes. As an example, RIPPLE automatically assigns all duties to the CI however, the DTL requires manual assignment of tasks. It will be important to ensure the QI/CI role, as well as other roles, are clear and consistent on the Participants List.

Notifications/Reminders

Notifications/reminders will be sent for outstanding issues and actions. These include:

1. **CI approval reminder email to CI-** Sent to the QI/CI when the DTL requires approval when updated or added tasks require QI/CI sign-off regardless of DTL status
2. **CI approval reminder email to DTLAs-** Sent to the DTLAs when the DTL requires approval by the QI/CI when updated or added tasks require QI/CI sign-off regardless of DTL status
3. **Participant added to PL (DTL components) but credentialing requirements not met-** Sent to the Participant and the DTLAs when credentialing checks are not passed when added to the DTL in RIPPLE, or when the NCI DTL sends a message back to RIPPLE about a credentialing failure.
4. **Participant does not have the required institutional roles to perform assigned task-** Sent to CCTG staff to indicate that participant does not have the required roles assigned in RSS to perform the task assigned. This will be resolved by CCTG, no action is required by the participant.
5. **Participants List (DTL component) now "unapproved" and accrual on hold-** Sent to DTLA(s) and QI/CI to notify of site-level DTL status change (approved to unapproved)
6. **New RIPPLE DTL components template version released – action required-** Sent to the DTLAs and CI when a new DTL Template Version is released with guidance for completion
7. **Participants List (DTL component) requires annual re-approval-** Notification to the DTLAs and QI/CI of required DTL Annual Re-approval. Sent at 30, 14 and 1 calendar day prior to the DTL no longer being active
8. **Site Registered and QI/CI approvals can now be completed-** Sent to the QI/CI when they can complete pending approvals
9. **RIPPLE Participants List (DTL) task active-** Sent to member once a task assignment status has changed to active
10. **RIPPLE Participants List (DTL) task now inactive**- Sent to member if a task assignment has changed from active to inactive to notify them that they should no longer be performing that task
11. **RIPPLE Participants List (DTL) task changed from Active to Pending status**- Sent to the member and the DTLA if a task assignment changes from active to pending to notify them to resolve the credentialing/training issue

10 APPENDIX I – RCR Types and DTL Tasks

TASK NAME	TASK DESCRIPTION	ALLOWED REGISTRATION TYPE				REQUIRED? [1]	MAX ALLOWED	REQUIRES ROSTERING? [2]	RSS INSTITUTIONAL ROLE REQUIRED [3]
		IVR	NPIVR	AP	A				
Clinical Investigator (CI)	Investigator at site responsible for signing the DTL for a given protocol and with overall responsibility for the study conduct at the site	✓				Y	1	Y	
DTL Administrator	Person assigned by the CI to manage the DTL	✓	✓	✓		Y	2	Y	
Consenting Person	Person listed in OPEN as having responsibility for consent	✓	✓	✓		Y		Y	
Eligibility Assessment	Verification of eligibility	✓	✓			Y		Y	
End Point Assessment	Assess study end points	✓	✓			Y		Y	
Enrolling Person/Treating Investigator	Investigator listed in OPEN as having responsibility for subject treatment (aka, Enrolling Investigator)	✓	✓			Y		Y	
HP Assessments	Conducts Physical Exam and Assessments	✓	✓			Y		Y	
IND Prescribing	Responsible for writing an order for a patient that is a CTEP IND agent.	✓				Y		Y	
Investigational Product Accountability	Tracking of distribution and return of investigational	✓	✓	✓	✓	Y		N	
OPEN Registrar	OPEN registration write access	✓	✓	✓		Y		Y	Registrar
Rave CRA	Rave write access; responsible for data management and uploads of central monitoring documents; and using Rave-CTEP-AERS safety reporting tools.	✓	✓	✓		Y		Y	Rave CRA
Tox Assessment	Assesses adverse events	✓	✓			Y		Y	
Agent Prescribing	Responsible for writing an order for a patient that is not a CTEP IND agent	✓	✓			N		Y	
Drug Shipment Investigator	The investigator in OPEN that will received CTEP distributed agent for the enrollment	✓				N		Y	
Pathology Lab Support	Pathology lab support	✓	✓	✓	✓	N		N	
Patient Screening/Recruiting	Responsible for screening and recruiting of subjects	✓	✓	✓		N		Y	
Primary Study/Site Contact	The point of contact for the study	✓	✓	✓		N		Y	
RT/Imaging Support	RT/Imaging support (primarily TRIAD related, but could be other)	✓	✓	✓	✓	N		N	
Rave Investigator	Investigator assigned to sign-off on the CRFs in Rave. Currently, maintained as part of the RSS roles by the roster owner (on a participating roster at the site)	✓	✓			N		Y	Site Investigator
Regulatory Contact	Site staff responsible for regulatory submissions and maintaining essential documents	✓	✓	✓		N		N	
Source Documentation Completion	Responsible for collecting data on study-related assessments.	✓	✓	✓		N		Y	
Study-Related Interventions	Responsible for coordinating and/or administering study-related interventions and procedures	✓	✓	✓	✓	N		N	

[1] Required/mandatory tasks will appear on all study DTLs and must always have individuals assigned to them for the site DTL to become/remain approved. Other tasks will appear on the study DTL template ONLY if selected by the lead group. The DTL itself will indicate if additional tasks are mandatory and must be assigned

[2] Must be active in the institution's roster in the Regulatory Support System. This is managed by CCTG.

[3] Assignments are sent to CTEP by CCTG. To be assigned OPEN Registrar, RAVE CRA or RAVE Investigator tasks on the DTL, the corresponding institutional role must be assigned to that individual at the site for CTEP.