CTSU Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE
Linking practice to progress

CTSU Updates

Fall Site Operations Meeting

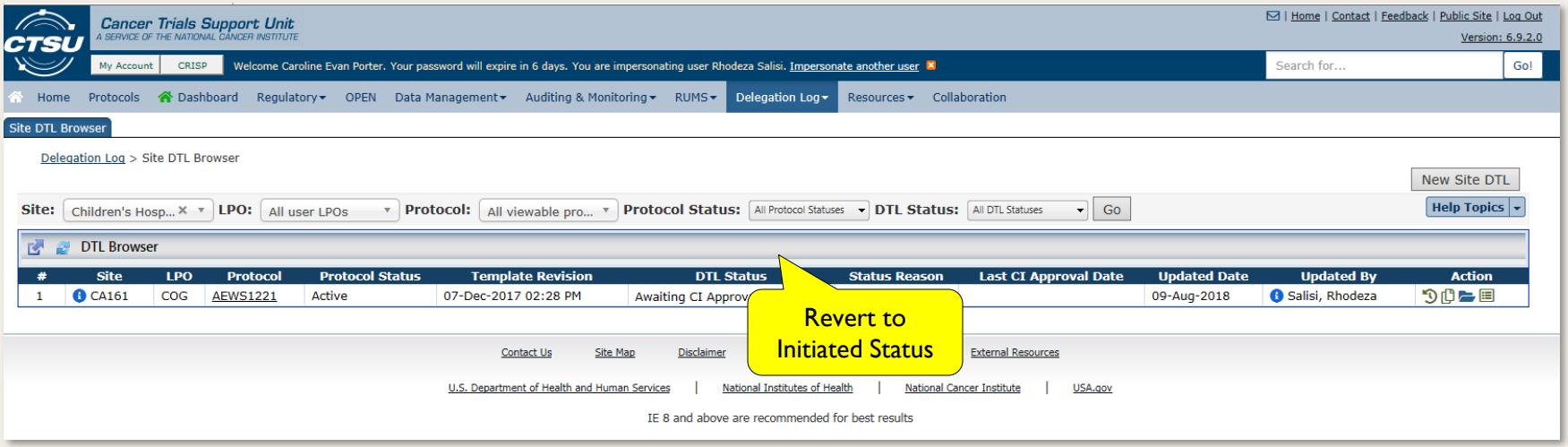
Agenda

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

DELEGATION OF TASKS LOG (DTL)

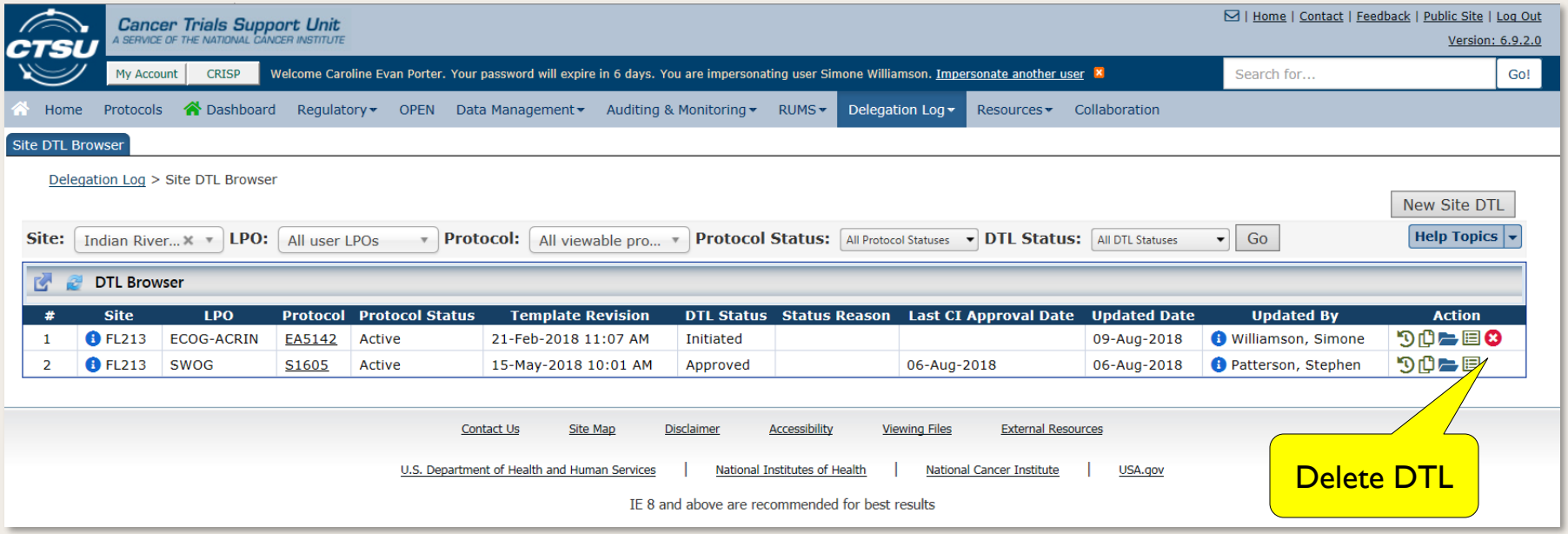
Revert DTL back to Initiated

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

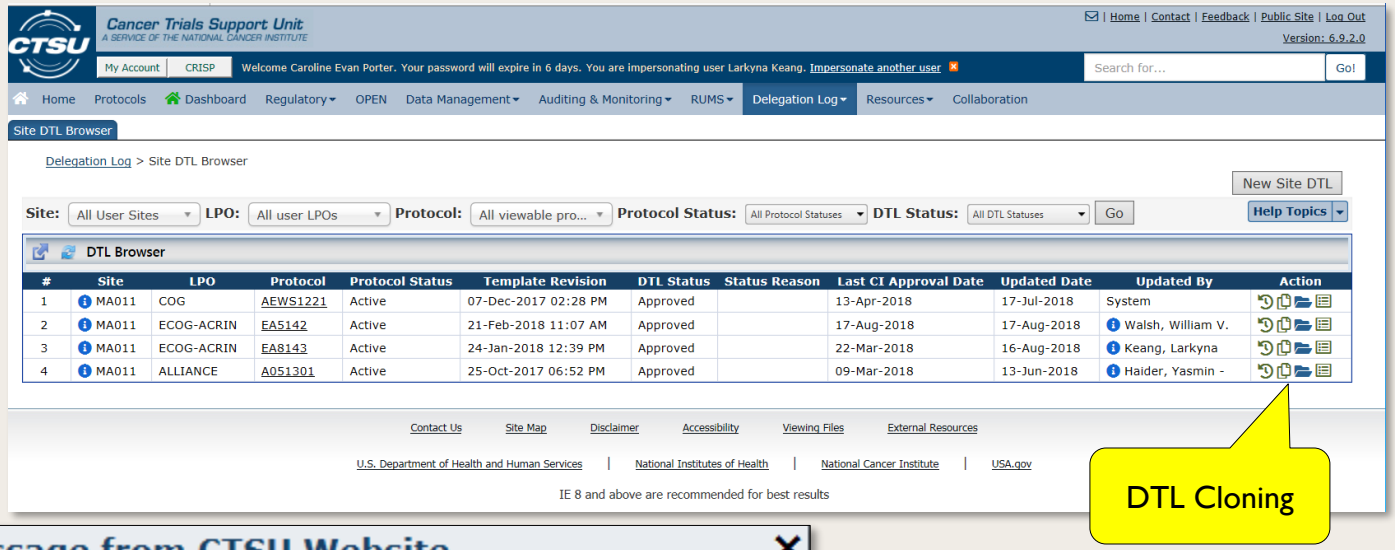


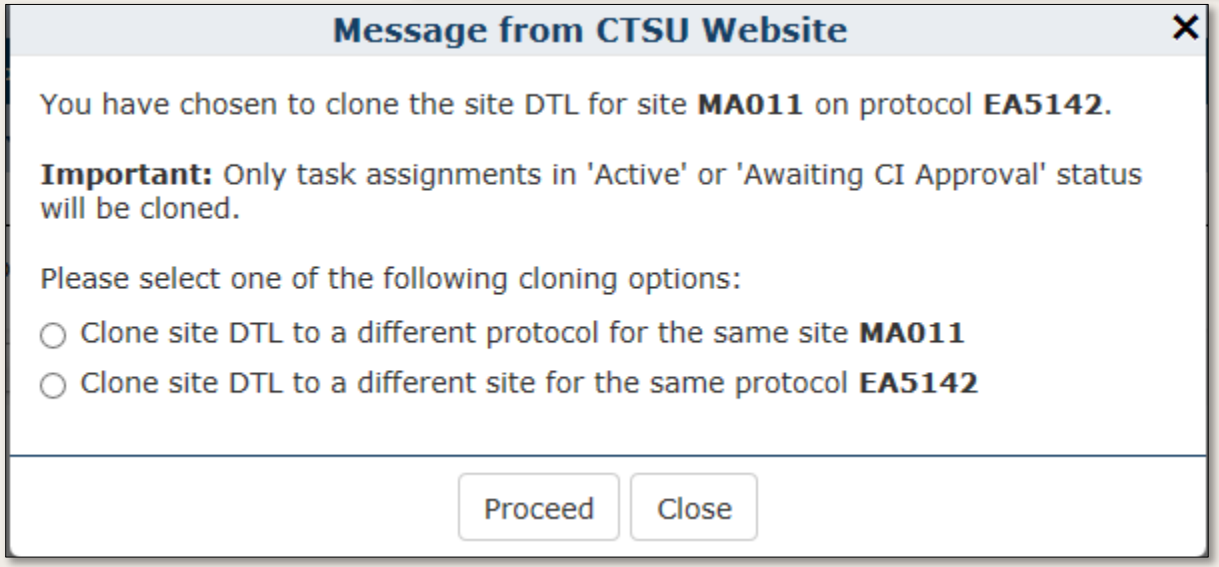
Delete a Site DTL

A DTL in Initiated Status can be deleted



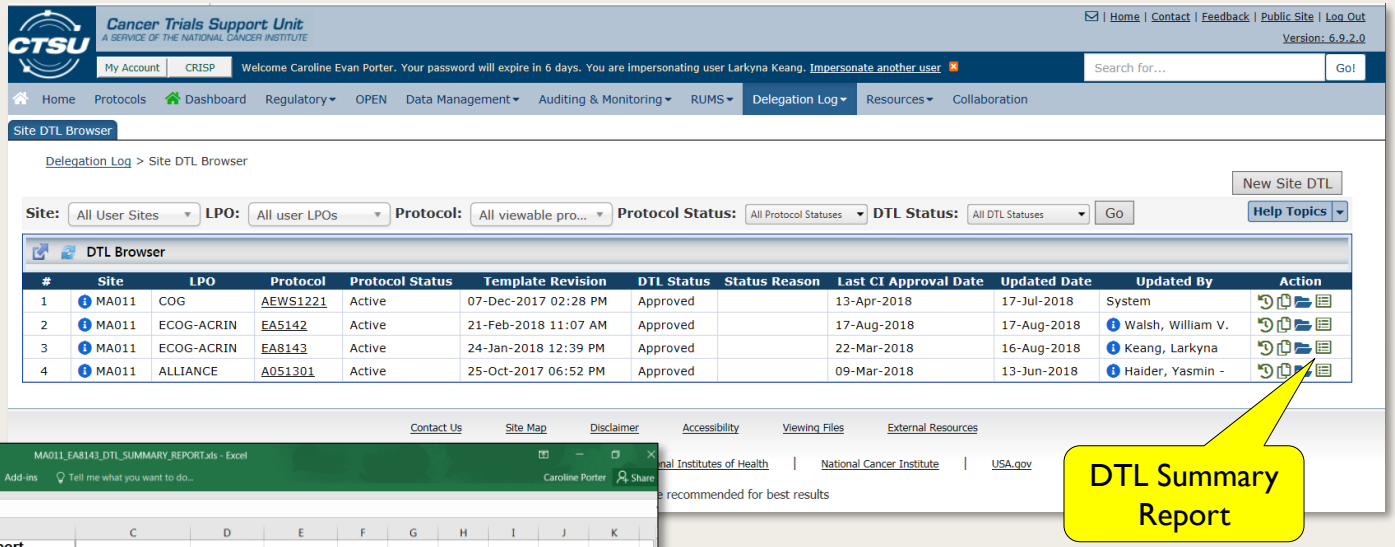
Changes for Cloning a DTL

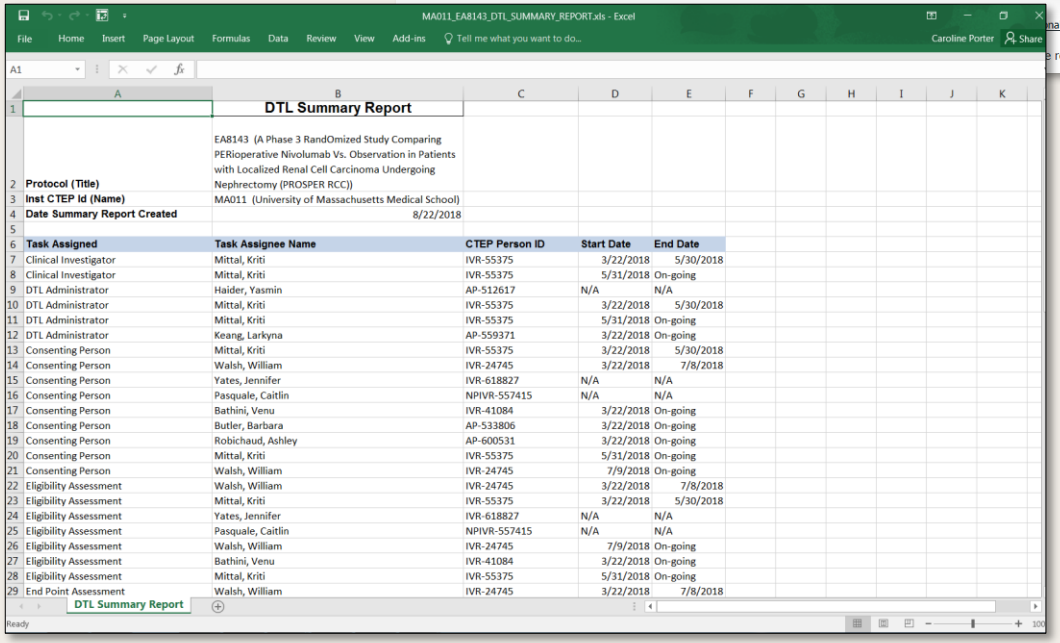




Only tasks in Active or Awaiting CI Approval status will be copied when a DTL is cloned

DTL Summary Report

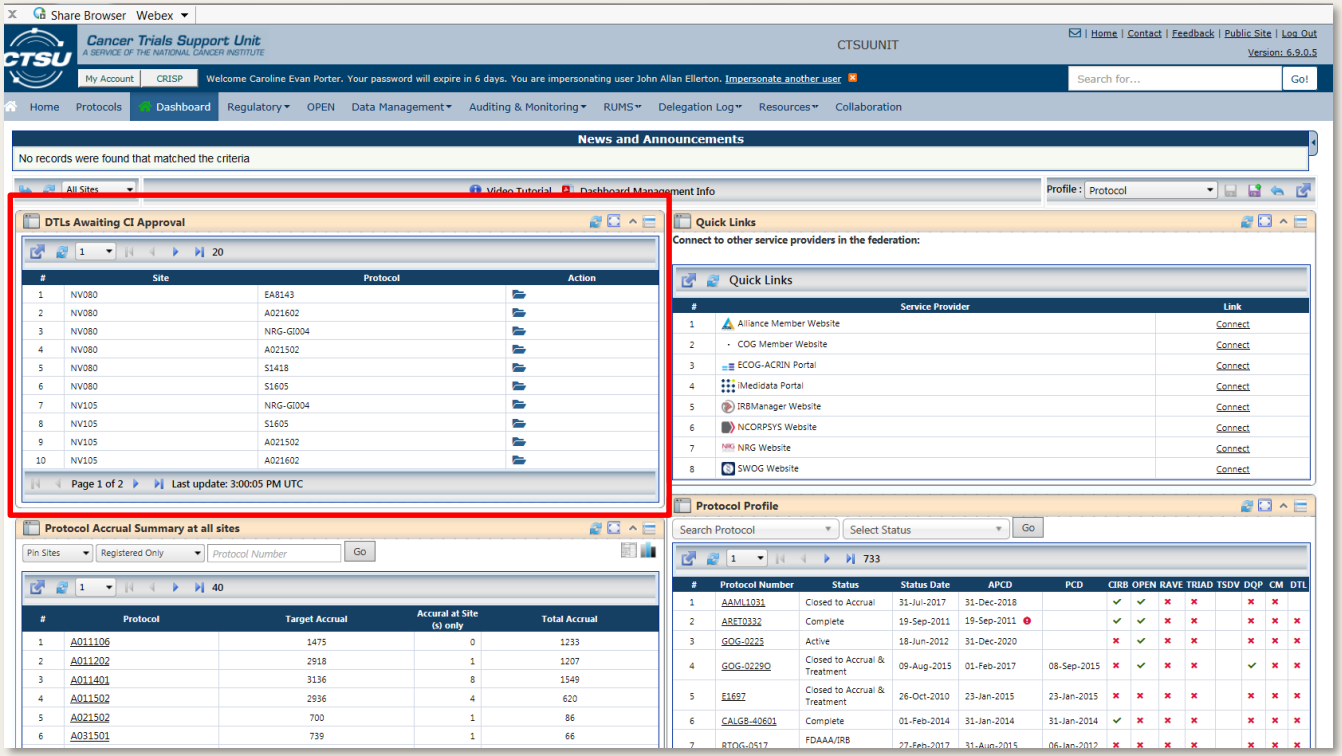




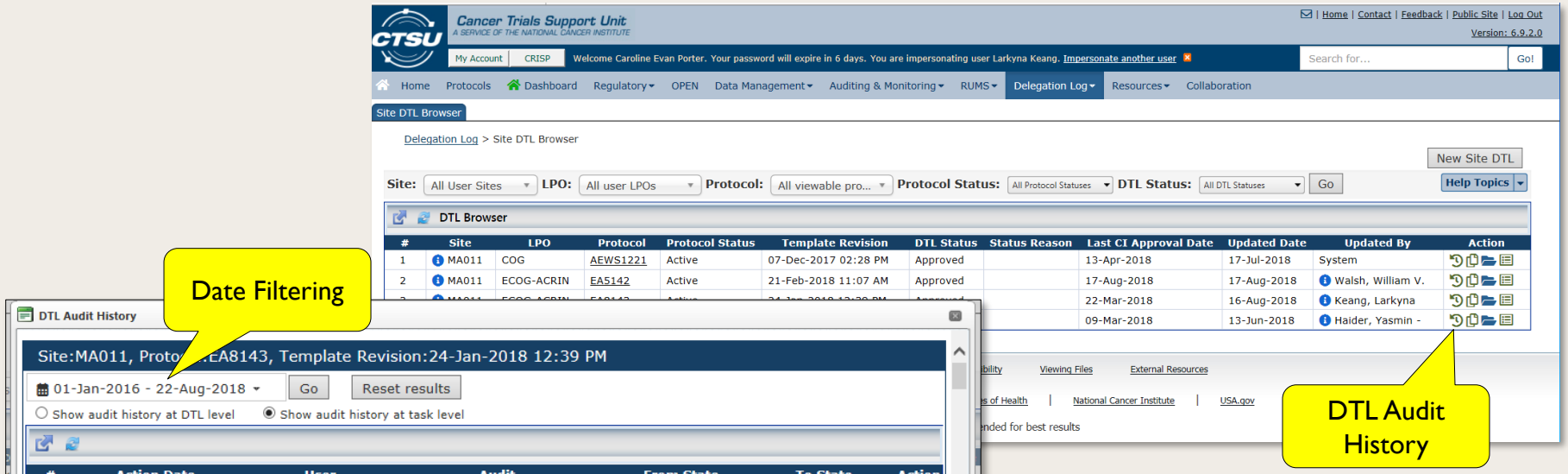
An Excel spreadsheet is available for sites to easily view all DTL assignments and status

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



DTL Audit History Improvements



Date Filtering

- 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 (1)

- 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

- 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 (1)

- 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 ??