Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE

Linking practice to progress

Cancer Trials Support Unit (CTSU) Service Overview

Center for Cancer Research (CCR) Clinical Research Forum - January 8, 2024

Presented by Martha Hering, MHA, CTSU Project Director

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Agenda

- Introduction and Overview of the CTSU
- National Cancer Institute (NCI) Research Networks and Other Players
- Using CTSU Support Services

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Slide 1

LP0 Introduce.
LaWanna Porcher, 2024-01-05T12:10:00.706

Introduction and Overview of the CTSU

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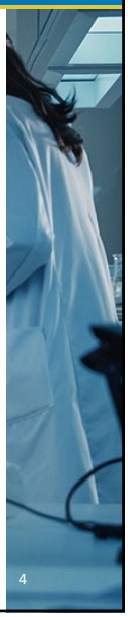
What is the CTSU

- The CTSU is a service of the NCI originally established in 1999 to facilitate participation in NCI cancer clinical trials as a recommendation of the Armitage report.
- It is an Indefinite Delivery Indefinite Quantity (IDIQ) contract directed by NCI's Division of Cancer Treatment and Diagnosis (DCTD), Cancer Therapy Evaluation Program (CTEP) with additional support/input from the Division of Cancer Prevention (DCP).



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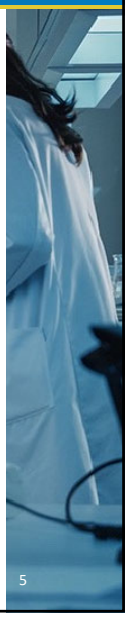
CTSU IDIQ Structure

- As of 2022, the CTSU IDIQ has several Task Orders (TOs) under multiple contractors:
  - TO 2A – CTSU Core Services and Enterprise of Systems (Westat)
  - TO 3A – Awareness, Education, and Training (AET) (EDJ)
  - TO 4A – Site Support Services (SSS) (Westat)
  - TO 5A – Protocol Writing Services (Technical Resources International (TRI))
  - TO 6A – electronic Patient Reported Outcomes (Westat)



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Mission

- The mission of the CTSU is to provide administrative, regulatory, logistical, and information technology support with the objective of gaining operational efficiencies for implementing multi-center clinical trials across the NCI-supported research networks; thereby increasing accrual and access.

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Goals

- Enhance the integration of information technology services supporting NCI's national cancer clinical trials program.
- Streamline and standardize clinical trials processes, including patient enrollment and data collection services.
- Reduce regulatory and administrative burden on investigators participating in NCI-sponsored clinical trials.
- Facilitate physician and patient access to NCI-sponsored clinical trials.

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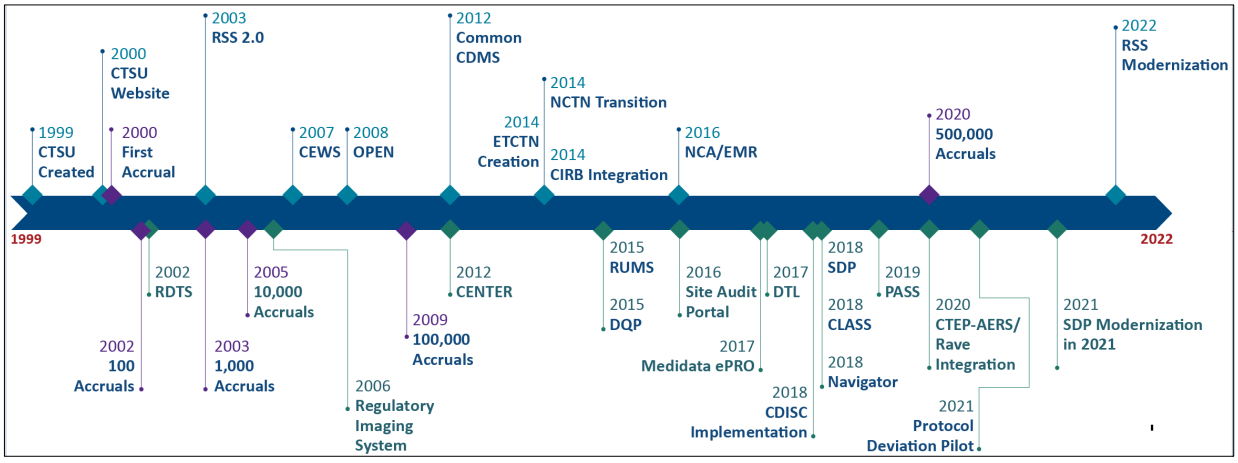
CTSU Timeline



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CTSU Core Services

- Regulatory Services
- Oncology Patient Enrollment Network (OPEN) Services
- Site Support Services
  - Help Desk
  - Membership
- Protocol Services
- Clinical Data Management System (CDMS) Support Center (CSC)
  - Rave-related standardizations
  - Rave-related integrations

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CTSU Enterprise System (CTSU-ESYS) by Function

CTSU Website	Regulatory Support	Roster Support	OPEN	Data Management and Quality Support	Communications, Reporting, and Training
• Protocol Documents • Educational Resources • Information Dissemination • Access Point	• Regulatory Submission Portal • Regulatory Application • Protocol Application • Delegation of Tasks Log (DTL)	• Roster Maintenance Application • Roster Update Management System (RUMS) • Provider Association	• Enrollment Module • Transfer and Update Module (T&UM) • Funding Module	• Rave Integrations • CTEP-Adverse Event Reporting System (AERS) Integration • Data Quality Portal (DQP) • Source Document Portal (SDP) • Site Audit Portal/Targeted Source Document Verification (TSDV) • Performance Assessment Score for Sites (PASS) • Navigator*	• Compliance, Learning, and Standard Operating Procedures, Solutions (CLASS) • Reports Applications • CTSU Enterprise Network Transaction Engine for Rave (CENTER) • CTSU Enterprise Web Services (CEWS) • Real-Time Data Transfer Service (RDTS)

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Key Incoming Integration Points

CTEP Study Abstraction Review and Tracking System (START) > Protocol Maintenance	• Study data: Title/number, phase, participants
CTEP-Identify and Access Management (IAM) > Roster Maintenance	• Name, identifier, contact information, authentication
CTEP Registration and Credential Repository (RCR) > Roster Maintenance	• Registration information, licensing verification, practice sites, etc.
CTEP Enterprise Core Module (ECM) > Roster Maintenance	• Site name, identifier, and address
CTEP-AERS > Rave/SDP	• Serious Adverse Event (SAE) processing
Central Institutional Review Board (CIRB) IRBManager > Regulatory Application	• IRB approvals
Imaging and Radiation Oncology Core (IROC) applications > Roster Maintenance	• Imaging and radiation center identification and credentialing

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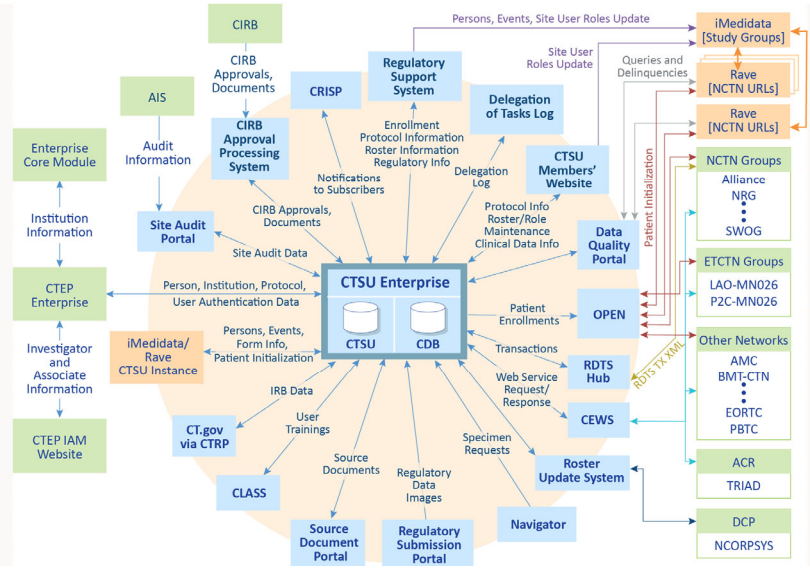
CTSU Enterprise with Integration Points



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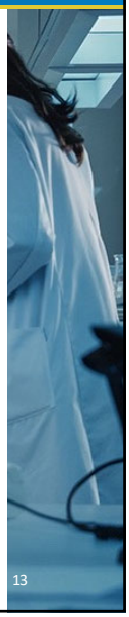
Other Services

- AET - CTSU Newsletter, protocol promotion, consent translations, and other training activities.
- SSS – National Coverage Analysis (NCA) and Electronic Medical Record (EMR) templates.
- Protocol Writing Services – Experimental Therapeutics Clinical Trials Network (ETCTN) protocol writing support.



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NCI Research Networks and Other Players

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NCI-Supported Networks/Consortia

National Clinical Trials Network (NCTN)	ETCTN	NCI Community Research Oncology Program (NCORP)	Other
• Alliance • Canadian Cancer Trials Group (CCTG) • Children's Oncology Group (COG) • ECOG-ACRIN • NRG • SWOG	• Lead Academic Organizations (LAOs) • Early Drug Development Organizations (EDDOs) • Early Drug Development Opportunity Program (EDDOPs)	• Wake Forest Research Base • University of Rochester Cancer Center (URCC) Research Base • NCORPs	• Pediatric Brain Tumor Consortia (PBTC) • AIDS Malignancy Consortia (AMC) • Pediatric Early Phase Clinical Trials Network (PEP-CTN) • Cancer Immunotherapy Trials Network (CITN) • NCI Center for Cancer Research (NCICCR) • NCI Development Therapeutics Clinic (NCIDTC)

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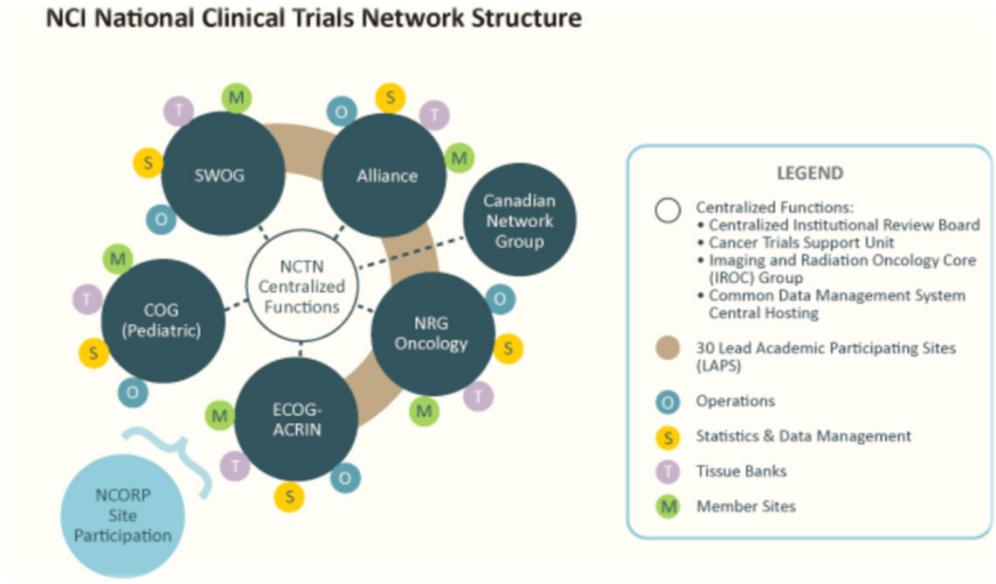
NCTN Format



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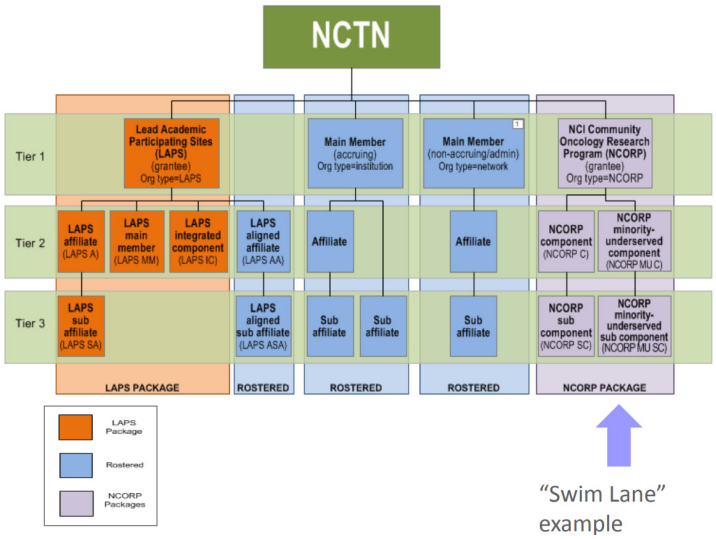
NCTN Organization Chart



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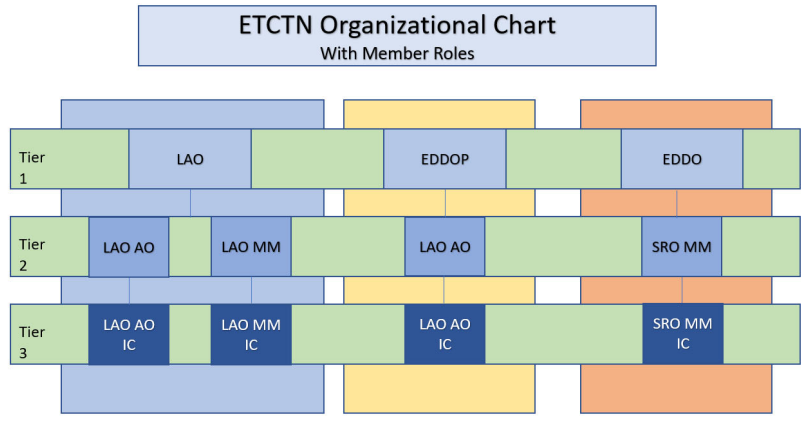
ETCTN Organizations



LAO = Lead Academic Organization
AO = Affiliated Organization
IC = Integrated Component
EDDOP = Early Drug Development Opportunity Program
EDDO = Early Drug Development Opportunity
SRO = Supplemental Research Organization

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Where does the Clinical Center Fit

For the NCTN

- MD004: Alliance Affiliate under Walter Reed (MD001)
- MD004: COG, ECOG-ACRIN, and NRG Main Member

For the ETCTN

- NCICCR and NCIDTC are enrolling sites under LAO-NCI

For Other Networks

- MD004: PBTC Main Member
- MD004: CITN Main Member
- MD004: PEP-CTN Main Member
- MD004: NCICCR Main Member
- MD004: NCIDTC Main Member

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Okay - I am Confused

- The Clinical Center acts as both an enrolling site and Lead Protocol Organization (LPO):
  - MD004 as a clinical site under the NCTN, CITN, PBTC, PEP-CTN, NCICCR, and NCIDTC
  - As an LPO under LAO-NCI (enrolling under NCICCR or NCIDTC) or when NCICCR and NCIDTC lead a study as an independent entity (enrolling under MD004)
  - Determined by the network/grant under which the site is participating and funded

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Other Players – Support Services

- Centralized Support Services:
  - CTSU – Clinical Study Support (including TOs 2A, 3A, 4A, and 5A)
  - CIRB – Central IRB
  - IROC – Radiation and Imaging credentialing
  - Medidata Rave – Clinical Data Management System
  - Clinical Data Monitoring Service (CDMS)/Theradex – Support for enrollment and data management setup for the ETCTN and some NCICCR/NCIDTC studies

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Using CTSU Support Services

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As an LPO - Summary

- Manage rosters for LAO-NCI, NCICCR, and NCIDTC.
- Work with CTEP and the CIRB or local IRB to obtain protocol-level approval.
- Work with the Regulatory Office and the CTSU Protocol Specialist (PS) to set up and manage LAO-NCI, NCICCR, and NCIDTC-led studies.
- Set up and maintain DTL templates for CTEP Investigational New Drug (IND) studies.
- Work with Theradex to develop the trial in Rave, as applicable.
- Work with Theradex or the CTSU OPEN team to develop the registration forms in OPEN and Interactive Web Response System (IWRS), as applicable.
- Work with Theradex (as appropriate) to monitor data collection.

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As a Participating Site - Summary

- Manage your site roster with the NCTN, CITN, PBTC, and PEP-CTN.
- Work with the CIRB or the local IRB to obtain site-protocol approval.
- Submit local IRB approvals and any additional Protocol-Specific Requirement (PSR) to the CTSU Regulatory Office.
- Register patients through OPEN.
- Submit data through Rave (as appropriate) and monitor site performance.

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Steps for Rostering

- Obtain CTEP-IAM/ID.me.
- Register in RCR if an Investigator (IVR), Non-Physician Investigator (NPIVR), Non-IND/Non-Treatment (NINT), or Associate Plus (AP).
  - Be aware of Practice Sites, IRBs, and Labs
- Add the individual to the appropriate roster(s).
- Assign the appropriate person roles for access and contact.

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Managing Roster Affiliations

- Managing the LAO-NCI, NCICCR, and NCIDTC rosters:
  - RUMS or Roster Maintenance, that is the question.
  - Suggest using one or the other exclusively as the Clinical Center does not have independent child institutions.
  - Need to include any individual listed on the protocol cover page on the LPO roster if not rostered with the LPO.
- As a Participating Site – use RUMS or request the update from the LPO:
  - Alliance, ECOG-ACRIN, NRG, and the CIRB all allow maintenance through RUMS.
  - COG and PEP-CTN allow limited use.
  - CITN and PBTC do not use RUMS.

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CTSU Roster

- CTSU will roster Clinical Center staff to the CTSU roster at the appropriate LPO (e.g., LAO-NCI) and assign the access role.
  - Able to view information in CTSU applications across sites for which your organization leads.
  - Need an Authorizer to make updates.
  - Available Roles

Role	Write Access	Read Access
LPO_Staff	DTL Template	Most CTSU applications
LPO_Protocol Specialist (PS)	Update protocol status, Anticipated Primary Completion Date (APCD) and Primary Completion Date (PCD), Create DTL Templates	Most CTSU applications
LPO_Roster Admin (ROA)	Update roster data	Most CTSU applications

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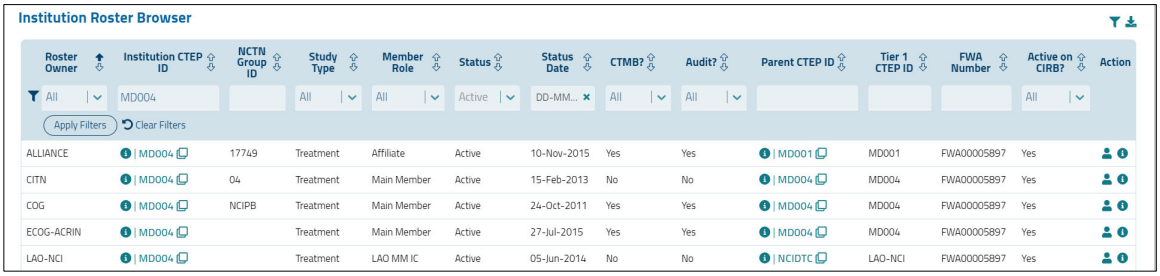
Rostering Hints

- Assign same individuals to manage rosters to keep things as consistent as possible.
- You can view across rosters in the Roster Maintenance application.
- Work with CTSU membership to address questions/concerns.



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Managing Regulatory/Protocol Setup as an LPO

- Follow the checklist for Steps for Coordinating Centers to OPEN ETCTN Trials.
- Specific to the CTSU:
  - The CTSU PS will provide comments to Protocol Information Office (PIO) as part of the protocol review.
  - Set up the protocol-specific DTL Template.
  - Work with the CTSU to review the NCA and EMRs.
  - Work with the CTSU Regulatory Office and PS for the protocol setup and study activation.
  - Work with the CTSU to activate the study or amendment and prepare/distribute the study/amendment memo or notification.

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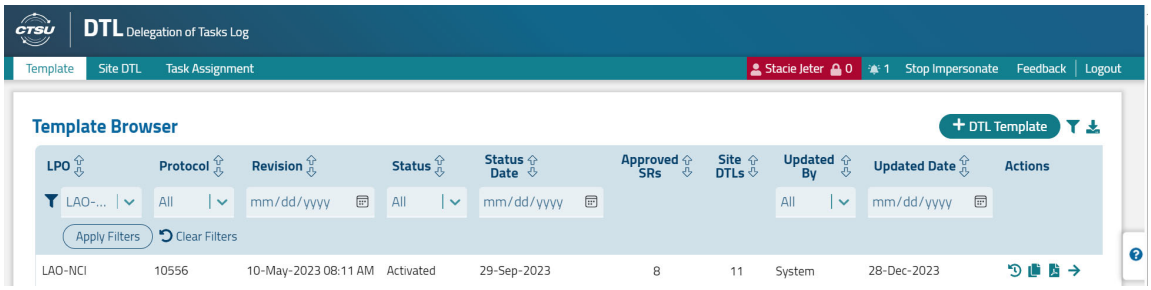
DTL Template

- To access the DTL Template, you must have an active LPO_PS or LPO_Staff role on the CTSU roster.
- Generally, will set up the DTL at the CTEP protocol approval on-hold status.
- Follow the standard setup to the extent possible.



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Protocol Setup/Activation

- The CTSU Regulatory Office will send a standard template email to collect information on the initial version of the protocol, agent (if not under a CTEP IND), and any needed PSRs.
- Theradex submits the OPEN-Rave Request form to complete the protocol setup.
- The CTSU PS will work with you to prepare for the activation.
- The CTSU PS will ensure all documents are posted to the website, prepare the notification, and add the trial to the CTSU Bi-Monthly Broadcast.

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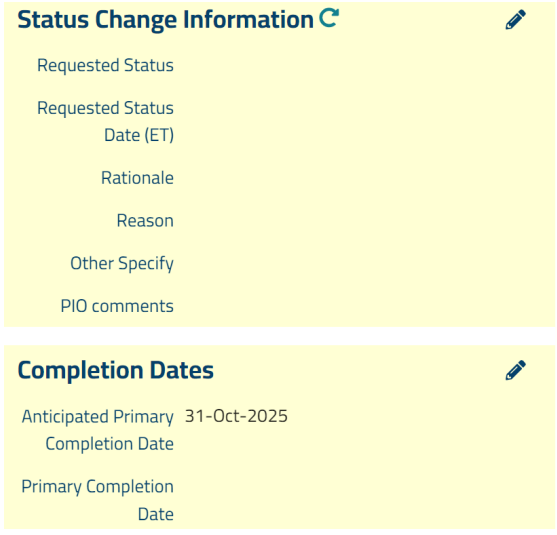
Setting the Protocol Status, APCD, and PCD

- Use the Protocol application:
  - Must be on the CTSU roster associated with the LPO and hold the LPO_PS role.
- Set the Anticipated Primary Completion Date (APCD):
  - It can be updated throughout the study lifecycle.
- Do NOT set the Primary Completion Date (PCD) until the study reaches its primary completion date!
- The APCD and PCD dates integrate with CTEP's systems and ultimately CT.gov.



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Participating Site – Regulatory Process

1. Access the study on the CTSU website and review.
2. If the study is reviewed by the CIRB, submit the Study Specific Worksheet to IRBManager, and ensure the Annual Signatory Institution Worksheet and Principal Investigator Worksheet are up-to-date.
3. Contact the Regulatory Office to set the Site Preferences (CIRB-MD004 is set as Protocol-Specific).
4. Submit any additional PSRs through the Regulatory Submission Portal and complete the DTL (if applicable).

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Other Activation Resources

- Review the NCA and EMR templates.
- Review any available protocol-specific materials or consent translations, if available.
- Use the Site Registration Browser or Website to view site registration statuses.
- Use the Person Browser to review person affiliations and roles.

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Managing OPEN as an LPO

- For the ETCTN – work with Theradex to develop the eligibility checklist form.
- For non-ETCTN – if using OPEN, work with Theradex if they are responsible for the protocol development or CTSU if using the CTSU RandoNode.
- As an LPO, you can view all accruals to studies that the Clinical Center leads.

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OPEN Tips as a Participating Site

- Ensure staff associated with MD004, NCICCR, or NCIDTC are rostered and hold the Registrar role.
- Treating/Credit investigators must be rostered with the correct site code, but do not require any special role.
- If there is a DTL, the Registrar, Consenting Person, and Treating Investigator must be on the DTL.
- The correct site code must have regulatory approval to select the site in OPEN and be listed as the lead or a participating site for the study.
- Use the Practice mode as needed.

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Data Management as an LPO

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- For the ETCTN – work with Theradex and their web reporting tool.
- Data Quality Portal (DQP) - review study level reports.

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Data Management Tips as a Participating Site

- Ensure staff are registered to the correct site with the correct Rave role:
  - Rave CRA role to enter subject data and respond to queries;
  - Rave Read Only role to view data;
  - Rave Investigator role to enter subject data, respond to queries, and sign;
  - Rave CRA (LabAdmin) role to enter subject data, respond to queries, and maintain local lab data; or
  - Rave SLA role to view data and maintain local lab data.
  - If there is a DTL, must have the DTL Rave CRA/Rave Investigator task assigned to access the study.
- Complete required Rave-related trainings including specimen trainings.
- As appropriate, use the DQP to view site-level data.

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Slide 37

MH0 This is mostly on the Theradex side, but they must provide some resources for the lead-LAO
Martha Hering, 2024-01-02T17:17:44.798

Kc0 0 Theradex has a CTMS-Rave-User Guide (https://www.theradex.com/cmsAdmin/uploads/ctms-rave-user-gu and other materials posted on this page: https://www.theradex.com/national-cancer-institute-nci/
Krishna Chothwani, 2024-01-02T19:24:11.708

Other Resources

- Under the Resources link
  - ETCTN Resources
  - CTSU Operations Information:
    - CTSU Training Modules
    - Help Topics/User Guides
    - CTSU Forms
- Translated Short-Form Consents
- NCTN and ETCTN Disease Portfolios
- FAQs, Glossary, and Acronyms
- LPO Resources

Thank You

Questions?