

Dear CTO/CRSL Colleagues,

We are reaching out to provide another update on the Clinical Trials Operational Planning initiative. Our aim is to keep you up to date on ongoing and emerging priorities. As always, if you have questions regarding this initiative, please reach out to ctoplanning@yale.edu.

Clinical Trials Operational Planning Update

The Design Phase continues with the Transformation Team and Workflow team discussing recommendations, making decisions, and creating and/or revising supporting documentation.

The other week select stakeholders gathered in New Haven for a full day project Leadership Retreat focused on Change Management and Change Leadership. The Transformation Team hopes to share some of their favorite lessons learned soon!

The Transformation Team is in the process of identifying the Step 1 Advisory Team members, and if you were selected you will be reached out to individually to confirm your participation.

Please continue to check our website, which is updated biweekly:
[YCC Clinical Trials Operational Planning < Yale Cancer Center](#)

Questions about the Operational Planning project can be sent to ctoplanning@yale.edu.

eRegulatory (eReg) Optimization

The eReg optimization team has finished the in-scope Lung DART protocols and are currently working through the in-scope Breast and GI DART protocols. Preparations for the Leukemia DART will begin shortly. The quality review team now has access to Epic and are re-reviewing some outstanding items, we anticipate this will reduce the number of issues being sent out. However, we request that you continue to address issues within the requested deadline so that optimization can be marked complete.

The eReg Quick Tip this week (attached) outlines the process to remove staff members from the Delegation of Authority Log while allowing them to remain on the protocol staff list. Please follow this process for any staff members that need access to the eReg protocol, but do not need to be listed on the DOA.

Questions regarding eReg optimization can be sent to shannon.chism@yale.edu

Other CTO Updates

The following upcoming training modules are scheduled on the CTO Training Calendar within Outlook.

- **Oncology CE Series – Supportive Care Medications:** Thursday, April 14th, 12:00-1:00 PM
- **Tumor Type Series – Leukemia:** Monday, April 18th, 3:00-4:00 PM
- **Tumor Type Series – Bladder Cancer:** Wednesday, April 20th, 9:30-10:30 AM

- **HIPAA Refresher:** Wednesday, April 20th, 11:00 AM-12:00 PM (need to pre-register in TMS)
- **Writing an Effective Informed Consent:** Thursday, April 21st, 12:00-1:00 PM (need to pre-register in TMS)

If you have any questions or concerns about training and education, please reach out to Melanie Anderson (melanie.anderson@yale.edu).

Thank you for your continued engagement in this initiative!

Sincerely,

Core Team:

Alyssa Gateman (YCC)
Margaret Gilshannon (YCC)
Leah Guidry (Huron)
Ian Krop (YCC)
Erin Pennington (Huron)
Adam Roshka (YCC)
Nirmala Thevathasan (YCC, Interim)

Project Management Office

Shannon Chism (Huron)
Kristi Godbolt (Huron)
Ryan Maxwell (Huron)
Cheryl Majeske (Huron)
Erin Pennington (Huron)