

Dear 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 Transformation Team continues to meet weekly to discuss key decisions regarding Step 1 of the CTO Planning Initiative. Several decisions have been made as an outcome of these meetings:

- The YCC CTO will implement “Career Ladders” for multiple clinical operations positions. Career Ladders will provide additional career advancement opportunities within the CTO, as well as increase workforce stability. The ladders themselves are currently in design and more details will be announced in the coming months.
- The Steering Committee has approved the creation of support role(s) to assist YCC investigators with the development of Investigator Initiated Trials (IITs). IITs are essential to YCC and our research mission, and by providing dedicated resource(s) we can help you in this important area. Additional information to come!
- The membership for the Step 1 Advisory Team has been finalized. This Advisory Team will review approved materials and provide feedback on the design and implementation plans from a community stakeholder standpoint.

The members include:

Jazmin Figueroa-Bodine	Katie Kelley	Jen Pope	Diane Wall
Patti Brand	Julie Lecco	Zia Rahman	Christina Wiess
Anne Caldwell	Rebecca Lilian	Jaime Rotatori	Katie Wildman
Diane Eannotti	Maureen Major Campos	Kert Sabbath	Danyell Williams
Rachel Hurtado	Talia Mitchell	Lauren Slater	
Barb Johnson	Kira Pavlik	Roberta Sterling	

Because of the need to keep the Advisory Team to a manageable size, we regret that not everyone who volunteered could be selected. If you volunteered and were not selected for Step 1, you will automatically be considered for the Advisory Teams in Steps 2-4.

We will continue to communicate updates as progress is made, but hope these changes begin to generate some excitement as the design phase moves forward.

If you have any questions about the Operational Planning project, please reach out to ctoplanning@yale.edu.

eRegulatory (eReg) Optimization

The eReg optimization team is finishing up the in-scope GI DART protocols and have started working through the in-scope Leukemia DART protocols. Preparation for the Head & Neck/TRAD and Neuro-Oncology DARTs will begin soon.

The Quality Review team continues to review studies and work with teams to resolve items. We are looking to create additional tools (guidance documents and job aides) to support the resolution of items. If you have thoughts or suggestions that would be helpful, we would like to hear from you.

The attached eReg Quick Tip continues working through common Delegation of Authority issues and resolutions. This week, the focus is on reconciling staff members on the Delegation of Authority log who have left the University.

Questions regarding eReg optimization and quality review suggestions 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.

- **Meet the Leadership – Yale IRB Chairs:** Wednesday, May 11th, 12:00 -1:00 PM (need to pre-register in TMS)
- **GCP Refresher Course:** Monday, May 16th, 1:00-4:00 PM (need to pre-register in TMS)
- **HIPAA Refresher Course:** Wednesday, May 18th, 11:00 AM -12:00 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)