

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 Transformation Team and Workflow Team met in person the week of April 11th for two half-day intensive sessions. Several decisions were made as an outcome of those meetings, including:

- Selected Ontario Protocol Assessment Level (OPAL) as the staffing acuity tool. Learn more about OPAL in this [NIH Article](#).
- Decided to adopt the Joint Task Force for Clinical Trial Competency Framework into the design competency model. Learn more about the [Joint Task Force](#).

Selection of the Step 1 Advisory Team members has been finalized. If you were selected for participation, you will be contacted in the coming weeks.

Please continue to check our website, which is updated regularly:
[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 Breast DART protocols and is currently working through the in-scope GI DART protocols. The next DART in the queue is Leukemia, which is tentatively scheduled to begin the week of 5/2.

Kudos to the Phase I team for being the first DART to complete optimization and resolution of a portion of studies within their scope. We understand this is an undertaking but encourage everyone to follow up with the Quality Review team to closeout items so that optimization can be marked complete.

The attached eReg Quick Tip works through common problems associated with the Delegation of Authority Log and how to resolve them. The issues discussed this week involve updating staff member start dates when the correct date is before the original date entered.

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

Other CTO Updates

- Welcome back to Diane Eannotti! We're excited to have her back to help continue moving the training and education initiatives forward.

- As many of you know, Jessie Pierre has left Huron to pursue other opportunities. We were very fortunate to have Jessie work on the Yale engagement and wish her all the best in her future endeavors. In Jessie's absence, please reach out to the following individuals for any inquiries in the interim:
Training and Education: [Melanie Anderson](#)
Activation Project Managers: [Sara Raboin](#) and [Trisha Burrello](#)
- There is an upcoming webinar, **How to Speak with Your Boss about Your Career Goals**, scheduled for **Tuesday, May 3rd 12:00-1:30 PM**. Please [pre-register here](#) if you would like to attend.

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)