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. You can expect to receive similar updates regularly. As always, if you have questions regarding this initiative, please reach out to ctoplanning@yale.edu.

Clinical Trials Operational Planning Update

Project activity was slowed in February to allow the new leadership team: Drs Winer and Krop, supported by interim CTO administrator Nirmala Thevathasan, to onboard; however, the transition to the Design and Implementation phase is once again moving full steam ahead.

In March, the Steering Committee was revised to support more nimble decision-making. The team is Steering Committee is meeting more frequently. The new committee is chaired by Dr. Krop and includes:

- Eric Winer
- Ian Krop
- Arnim Dontes
- Alyssa Gateman
- Margaret Gilshannon
- Nirmala Thevathasan
- Lori Pickens
- Roy Herbst
- Adam Roshka
- Barbara Burtness

The Steering Committee has approved a more agile approach for the Design and Implementation Phases of the project, which will allow us to parse out the work into four steps and reach results more quickly.

This necessitated some retooling of our plans around Advisory Teams. We have formed two groups responsible for driving the design and implementation work, a Transformation Team and a Workflow Team. They join the already formed Communication Team comprised of key stakeholder representatives and chaired by Dr. Stein. A yet to be formed fourth Advisory Team comprised of select CTO Staff and faculty will serve as a focus group to review and provide feedback to the plans produced by the Transformation and Workflow Teams. Membership in this group may rotate based on the plans being reviewed.

A formal kick-off for the Design and Implementation Phase are being planned for multiple sessions to give additional details about the vision for the CTO, the role of each of these teams, and how you can engage in the process. We are formalizing dates for both faculty and CTO sessions in mid-to-late March.

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

eRegulatory (eReg) Optimization

The eReg optimization team has updated 66 out of 70 Phase I protocols and began optimization on 4 of 21 studies within the Lung DART. The next DART will be Breast, expected kickoff will be March 21st.

This week's **quick tip** is a reminder on how to update staff start dates in eRegulatory. The steps for managing staff start dates depend on if the staff is linked or unlinked with OnCore. See the attached Updating Staff Member Start Dates for step-by-step instructions.

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

Rapid Assessments

As previously mentioned, the Huron project team is undertaking two (2) small rapid assessment projects in parallel with the broader Clinical Trials Operational Planning initiative.

Updates for the two (2) rapid assessment projects include:

1. Study Intake: The Study Intake process is being standardized as part of the DART Review Process and will capture a minimum footprint of new studies. Data elements to be captured include basic study descriptors and investigator's level of interest in pursuing the study.
2. Disease-Aligned Research Team (DART) Review Process: The enhanced DART Review Process includes an enhanced Study Review Form completed by the investigator and Project Manager, to capture pertinent study information prior to DART review. In addition, a DART Protocol Prioritization Form has been created and finalized with feedback incorporated from multiple investigators and key leaders. The Protocol Prioritization Form will be used to critically evaluate and document the scientific value and impact of a study, to assist DARTs with prioritizing studies that will be forwarded to the Protocol Review Committee (PRC) and to ultimately assist them with study portfolio management. This will get YCC closer to achieving the National Cancer Institute's expectations of DARTs.

Next Steps: This new approach will be piloted across all DARTs in a paper format this month. The team is currently creating these processes within an electronic system (REDCap) with a go-live in the coming weeks.

Questions regarding the Rapid Assessments can be sent to nirmala.thevathasan@yale.edu.

Other CTO Updates

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

1. Theradex Training Course 2 – Con Meds, AEs, and Lab Results: Monday, March 14th, 2:00-3:00 PM

2. Tumor Type Series – Prostate Cancer: Tuesday, March 15th, 11:00 AM-12:00 PM

3. HIPAA Refresher: Wednesday, March 16th, 11:00 AM-12:00 PM (need to pre-register in TMS)

4. Tumor Type Series – Colorectal Cancer: Wednesday, March 16th, 3:00 PM-4:00 PM

5. Tumor Type Series – NSCL: Tuesday, March 22nd, 11:00 AM-12:00 PM

6. Tumor Type Series – BMT: Wednesday, March 23rd 3:00 PM-4:00 PM

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