

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](mailto:ctoplanning@yale.edu).

### **Clinical Trials Operational Planning Update**

Design kick-off sessions were held last week for faculty, staff, and CTO managers. If you were unable to attend one of these sessions, the slides can be found on the website later this week. [YCC Clinical Trials Operational Planning < Yale Cancer Center](#)

Three of the four Design teams (Transformation, Workflow, and Communications) working on the project are in full swing with decision making, organizational model design, and supporting documentation creation for Step 1. The scope of Step 1 includes:

- Clarification and changes to YCC CTO Leadership roles and responsibilities
- Clarification and changes to YCC Clinical Operations roles and responsibilities
- Clarifications and changes to the project management structure
- Quality and Education roles
- Introduction of a staffing acuity tool and rollout of career ladders for clinical operations
- Modifications to Study Conduct and Maintenance workflows

The Advisory Team for Step 1 is in development, and volunteers who are selected will be contacted in the coming weeks for participation.

Questions about the Operational Planning project can be sent to [ctoplanning@yale.edu](mailto:ctoplanning@yale.edu).

### **eRegulatory (eReg) Optimization**

The eReg optimization team is working through the in-scope Lung and Breast DART protocols. The next DART in the queue is GI tentatively scheduled for March 28<sup>th</sup>. The quality review team is actively reviewing protocols and sending items to be reviewed and resolved to the applicable CTTM and Regulatory teams. If you have received items for resolution, it is important to address them within the due date, optimization will not be complete until all issues are resolved.

The optimization team compiled a Frequently Asked Questions document to address questions and provide more information on why and how optimization is being handled (attached).

Questions regarding eReg optimization can be sent to [shannon.chism@yale.edu](mailto:shannon.chism@yale.edu)

### **Rapid Assessments**

With feedback and buy-in from multiple investigators and key leaders across the CTO and YCC, the DART Process Improvement launched on Monday 03/21/22, inclusive of an enhanced Study Review Form and a Protocol Prioritization Form (the Scoring Rubric), The Protocol Prioritization Form will help DARTs with critically evaluating and documenting the scientific value and impact of a study, and to assist them with prioritizing studies that will be forwarded to the Protocol

Review Committee (PRC). The overall goal of this process improvement is to assist DARTs with study portfolio management which is a National Cancer Institute expectation of DARTs.

This new approach will be piloted across all DARTs in a paper format with conversion to an electronic system (REDCap) in the coming weeks.

Questions regarding the Rapid Assessments can be sent to [nirmala.thevathasan@yale.edu](mailto:nirmala.thevathasan@yale.edu).

### **Other CTO Updates**

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

1. CRC/CRN Meeting: Tuesday, March 29th, 3:00-4:00 PM
2. CRA Meeting: Wednesday, March 30th, 1:00-2:00 PM
3. Data Management 101: Thursday, March 31<sup>st</sup>, 11:00 AM – 12:00 PM
4. YCCI Instructor-led GCP - Audits & Inspections: Purpose, What to Expect, Consequences: Thursday, March 31<sup>st</sup>, 12:00-1:00 PM (need to pre-register in TMS)
5. eReg Training for Reg Coordinators and Managers: Monday, April 4<sup>th</sup>, 12:30-2:30 PM (need to pre-register in TMS)
6. Tumor Type Series – Kidney Cancer: Monday, April 4th, 3:00-4:00 PM

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

Thank you for your continued engagement in this initiative!

Sincerely,

#### **Core Team:**

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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)  
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