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 <a href="mailto:ctoplanning@yale.edu">ctoplanning@yale.edu</a>.

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

You will recall that the Clinical Trials Operational Planning project has two components – providing interim staffing to support ongoing CTO operations and performing a consulting project to assist Yale with designing a CTO that is built to support the current operations and sustain growth into the future.

The consulting portion of the engagement involves four phases: Assessment, Design, Implementation, and Refine. Preparations for the Design phase are underway. The Huron team continues to meet regularly with Dr. Winer, Dr. Krop, and the Core Team regarding the direction of this phase. More details will be provided in future communications.

#### eRegulatory (eReg) Optimization

The eReg optimization team has updated 53 out of 70 Phase I protocols, we expect to begin working with the Lung DART beginning on March 7<sup>th</sup>.

**Did You Know:** eRegulatory Coordinators can stop-date a staff member on multiple protocols at once? This is correct, when a staff member is promoted to a new role or leaves the organization you can stop them on all their protocols at the same time. Review the attached eReg Quick Tip – Stop-Dating a Staff Member on Multiple Protocols for more details.

### Other CTO Updates

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

- Tumor Type Series Sarcoma/Thyroid: Tuesday, March 1st 11:00 AM-12:00 PM
- Good Clinical Practice (GCP) Essentials: Study Conduct and Trial Monitoring:

Thursday, March 3rd 12:00-1:00 PM

- Tumor Type Series SCLCa: Tuesday, March 8<sup>th</sup> 11:00 AM-12:00 PM
- Tumor Type Series Pancreatic Cancer: Wednesday, March 9th 3:00 PM-4:00 PM

As a reminder, please attest to reviewing the updated Subject Eligibility SOP <u>here</u> and watching/attending the Subject Eligibility Training <u>here</u>. If you have not reviewed the <u>training</u> or <u>SOP</u>, they can be found on the intranet.

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

Thank you for your continued engagement in this initiative!

### Sincerely,

# Core Team:

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Dr. Roy Herbst (YCC)
Ian Krop (YCC)
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## **Project Management Office:**

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